# Interventions for treating proximal humeral fractures in adults (Review)

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[Intervention Review]

# Interventions for treating proximal humeral fractures in adults

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## ABSTRACT

### Background

Proximal humeral fractures are common injuries. The management, including surgical intervention, of these fractures varies widely.

### Objectives

To review the evidence supporting the various treatment and rehabilitation interventions for proximal humeral fractures.

### Search strategy

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register, the Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE and other databases, and bibliographies of trial reports. The full search ended in March 2010.

### Selection criteria

All randomised controlled trials pertinent to the management of proximal humeral fractures in adults were selected.

### Data collection and analysis

Two people performed independent study selection, risk of bias assessment and data extraction. Trial heterogeneity prevented meta-analysis.

### Main results

Sixteen small randomised trials with 801 participants were included. Bias in these trials could not be ruled out.

Eight trials evaluated conservative treatment. One trial found an arm sling was generally more comfortable than a less commonly used body bandage. There was some evidence that 'immediate' physiotherapy compared with that delayed until after three weeks of immobilisation resulted in less pain and potentially better recovery in people with undisplaced or other stable fractures. Similarly, there was evidence that mobilisation at one week instead of three weeks alleviated short term pain without compromising long term outcome. Two trials provided some evidence that unsupervised patients could generally achieve a satisfactory outcome when given sufficient instruction for an adequate physiotherapy programme.

Surgery improved fracture alignment in two trials but was associated with more complications in one trial, and did not result in improved shoulder function. Preliminary data from another trial showed no significant difference in complications, quality of life or

costs between plate fixation and conservative treatment. In one trial, hemiarthroplasty resulted in better short-term function with less pain and disability when compared with conservative treatment for severe injuries.

Compared with hemiarthroplasty, tension-band fixation of severe injuries using wires was associated with a high re-operation rate in one trial. One trial found better functional results for one type of hemiarthroplasty.

Very limited evidence suggested similar outcomes from early versus later mobilisation after either surgical fixation (one trial) or hemiarthroplasty (one trial).

**Authors' conclusions**

There is insufficient evidence to inform the management of these fractures. Early physiotherapy, without immobilisation, may be sufficient for some types of undisplaced fractures. It is unclear whether surgery, even for specific fracture types, will produce consistently better long term outcomes.

## PLAIN LANGUAGE SUMMARY

**Interventions for treating proximal humeral (top end of upper arm bone) fractures in adults**

Fracture of the top end of the upper arm bone is a common injury in older people. The bone typically fractures (breaks) just below the shoulder, usually after a fall. Most of these fractures occur without breaking of the skin. Often the injured arm can be supported in a sling until the fracture heals sufficiently to allow shoulder movement. More complex fractures may be treated surgically. This may involve fixing the fracture fragments together by various means. Alternatively, the top of the fractured bone may be replaced (half joint replacement: hemiarthroplasty), or sometimes together with the joint socket (total joint replacement). Physiotherapy is often used to help restore function.

This review includes evidence from 16 small randomised trials with a total of 801 participants. Several trials had weaknesses that could bias their results. No trials were similar enough to pool their results.

Eight trials evaluated conservative (non-surgical) treatment. One trial found an arm sling was generally more comfortable than a less commonly used body bandage. There was some evidence that 'immediate' physiotherapy compared with physiotherapy delayed until after three weeks of immobilisation resulted in less pain and faster recovery in people with 'stable' fractures. Similarly, there was evidence that mobilisation at one week instead of three weeks alleviated pain in the short term without compromising long term outcome. Two trials provided some evidence that patients could generally achieve a satisfactory outcome when given sufficient instruction to pursue exercises on their own.

Evidence from two trials did not show that surgery resulted in improved function, but it was associated with more complications in one trial. Preliminary data from a third trial showed no differences in complications or quality of life between fixation with a bracket and screws and conservative treatment. In another trial, hemiarthroplasty resulted in better short-term function and less pain when compared with conservative treatment for severe injuries. Another trial found that fixation of severe injuries by holding the broken fragments together with wires resulted in more reoperations than replacement with a hemiarthroplasty. One trial found better functional results for one of two types of hemiarthroplasty.

There was very limited evidence suggesting similar outcomes for early versus later mobilisation after either surgical fixation or hemiarthroplasty.

Overall, there is some evidence to support earlier arm movement for some types of fractures. Otherwise, there is not enough evidence to determine the best treatment, including surgery, for these fractures.

# BACKGROUND

## Description of the condition

Proximal humeral fractures account for approximately six per cent of all adult fractures (Court-Brown 2006). Their incidence rapidly increases with age, and women are affected about three times as often as men (Court-Brown 2006; Lind 1989). Many patients who sustain a proximal humeral fracture are old and their bones are osteoporotic. Court-Brown 2001 found that 87% of these fractures in adults resulted from falls from standing height.

Most proximal humeral fractures are closed fractures in that the overlying skin remains intact. The most commonly used classification of shoulder fractures is that of Neer (Neer 1970). Neer considered four potential segments of the proximal humerus - the articular part, the greater tuberosity, the lesser tuberosity and the humeral shaft. These may be affected by fracture lines but are only considered as a 'part' if displaced by more than one centimetre or 45 degrees angulation from each other. Fractures, regardless of the number of fracture lines present, which did not meet the criteria for displacement of any one segment with respect to the others were considered 'undisplaced' and categorised as one-part fractures. Neer's other categories, two-part, three-part and four-part fractures all involved the displacement of some or all of the above four segments. Each of these may be potentially associated with an anterior or posterior humeral head dislocation.

At initial presentation, it may be difficult to delineate the exact pattern of the fracture even with sophisticated imaging. In any event, this may not correlate with the degree to which avascularity (loss of blood supply) may develop within the humeral head. The vascularity of the proximal humerus is a secondary focus of another widely used classification system for these fractures, the AO classification system (Muller 1991), which was updated in conjunction with the OTA classification in 2007 (Marsh 2007). There are three main types (A, B, C), which in turn are further divided into three groups, each with a further three subgroups. Type A fractures are "extra-articular, unifocal, with intact vascular supply"; type B fractures are "extra-articular, bifocal, with possible vascular compromise"; and type C fractures are "articular, with a high likelihood of vascular compromise" (Robinson 2008).

Many proximal humeral fractures are not displaced or only minimally displaced. Neer's estimate (Neer 1970) that approximately 85% of all proximal humeral fractures are "undisplaced", in that no bone fragment is displaced by more than one centimetre, or angulated by more than 45 degrees is often cited (Koval 1997). However, a lower figure of 49% was reported in a prospective study of over 1000 proximal humeral fractures (Court-Brown 2001).

## Description of the intervention

Conservative treatment is generally the accepted treatment option for minimally displaced fractures, and frequently used for people with displaced fractures too. Conservative treatment usually involves a period of immobilisation, such as in an arm sling, followed by physiotherapy and exercises.

Surgery is usually reserved for displaced and unstable fractures and those with more complicated fracture patterns. Surgical interventions include:

- Closed reduction and percutaneous stabilisation using pins or wires
- External fixation
- Open reduction and plating: for example, buttress plates, angle blade plates and proximal humeral locking plates
- Open reduction and fixation using a tension-band principle
- Intramedullary nailing either antegrade or retrograde insertion; nowadays, intramedullary nail are 'locked' into place, generally using screws
- Hemiarthroplasty (replacement of the humeral head) or total shoulder replacement (replacement of joint socket too)

Post-operative treatment generally involves a period of immobilisation followed by physiotherapy and exercises.

## How the intervention might work

Immobilisation of the injured limb helps to maintain fracture stability and to provide pain relief during healing. However, there is a risk of the shoulder becoming stiff and painful with substantial reduction of function. Subsequent physiotherapy and exercises aim to restore function and mobility of the injured (or operated) arm. Malunion of proximal humeral fractures may result in impingement or compromised function of the muscles inserting into the proximal humerus.

After reduction or repositioning of the fractured parts, surgical fixation using various techniques aims to stabilise the reduced fracture and restore joint mechanics. Surgical stabilisation of the fracture may also allow earlier movement of the shoulder and elbow, preventing stiffness. Surgeons have often followed Neer's premise (Neer 1975) that in a four-part fracture head necrosis is virtually guaranteed and have offered their patients a replacement arthroplasty, where the humeral head alone, or in combination with the socket, is replaced by artificial parts. An exception is made for a specific type of four-part fracture, the valgus impacted four-part fracture, not mentioned in Neer's classification. This fracture, where the fractured parts are compressed towards each other, is less likely to lead to avascular necrosis of the humeral head, provided the lateral displacement of the head fragment is not excessive (Jakob 1991; Resch 1997). Bone quality also influences the appropriateness of any intervention and hence the long term clinical outcome. Furthermore, the patient's frailty may lead to a low rehabilitation drive and delay any recovery from both the initial trauma and any subsequent management.

### Why it is important to do this review

Proximal humeral fractures are increasing in incidence, particularly in older people, and the short and long term consequences for individuals with these injuries and society are substantial (Palvanen 2006). There is considerable variation in practice, both in terms of definitive treatment such as surgical treatment for displaced fractures (Guy 2010) and rehabilitation (Hodgson 2006). The previous version of this review noted the insufficiency of the evidence to inform practice, but also located ongoing trials that potentially could help address this deficiency (Handoll 2003b). This update continues the systematic review of the evidence for managing these fractures.

## OBJECTIVES

This review aims to determine the most appropriate treatment for fractures of the proximal humerus in skeletally mature people (adults).

We aimed to examine the evidence from randomised and quasi-randomised controlled trials for the effects (benefits and harms) of different treatment, including rehabilitation, interventions in adults with fractures of the proximal humerus. We defined a priori the following broad objectives:

- To compare different methods of conservative treatment (including rehabilitation)
- To compare surgical versus conservative treatment
- To compare different methods of surgical treatment
- To compare different methods of rehabilitation after surgical treatment

We planned to study the outcomes in different age groups (initially, under versus over 65 years) and for different types of proximal humeral fractures.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

All randomised or quasi-randomised (method of allocating participants to a treatment which is not strictly random; e.g. by hospital record number) trials which compared two or more interventions in the management of fractures of the proximal humerus in adults.

#### Types of participants

Patients of either sex who had completed skeletal growth, with a fracture of the proximal humerus. Stratification was planned by fracture type (e.g. based on the Neer classification (Neer 1970)) and by age (under versus over 65 years) if possible.

#### Types of interventions

Conservative and surgical interventions, as presented in 'Background', used in the treatment and rehabilitation of fractures of the proximal humerus. Pharmacological trials were excluded.

#### Types of outcome measures

The primary focus is on long term functional outcome, preferably measured at one year or more.

##### Primary outcomes

1. Functional outcomes: Patient-reported measures of upper-limb function (e.g. the Disability of the Arm, Shoulder, and Hand questionnaire (DASH) and other validated shoulder rating scales), activities of daily living and health related quality of life scores.
2. Serious adverse events (e.g. death, deep infection, avascular necrosis, complex regional pain syndrome), and need for substantive treatment, such as an operation

##### Secondary outcomes

1. Pain
2. Upper limb strength and range of movement
3. Other complications
4. Patient satisfaction with treatment, including cosmetic outcomes
5. Anatomical outcomes, e.g. radiological deformity

Economic outcomes: each trial report was reviewed for costs and resource data, such as length of hospital stay and number of outpatient attendances, that would enable economic evaluation.

### Search methods for identification of studies

#### Electronic searches

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (February 2010), the Cochrane Central Register of Controlled Trials (in *The Cochrane Library* 2010, Issue 2), MEDLINE (1966 to March week 1 2010), EMBASE (1988 to 2010 week 10), CINAHL (EBSCO: September 2006 to 19 February 2010), AMED (Allied and Complementary Medicine) (1985 to March 2010), and PEDro - The Physiotherapy Evidence Database up to September 2006. The

first two sections of the Cochrane optimal MEDLINE search strategy for randomised trials (Higgins 2006) were combined with the subject specific search (Appendix 1). Search strategies for the Cochrane Central Register of Controlled Trials, EMBASE and CINAHL can also be found in Appendix 1. Details of the search strategies used for previous versions of the review are given in Handoll 2003b. No language or publication restrictions were applied.

We searched the WHO International Clinical Trials Registry Platform Search Portal (August 2010), Current Controlled Trials (August 2010), and the UK National Research Register (NRR) Archive (August 2010) to identify ongoing and recently completed trials.

### Searching other resources

We searched the reference list of articles. We also included the findings from handsearches of the British Volume of the Journal of Bone and Joint Surgery supplements (1996 to 2006) and abstracts of the British Elbow and Shoulder Society annual meetings (2001 to 2010), the American Orthopaedic Trauma Association annual meetings (1996 to 2009), American Academy of Orthopaedic Surgeons annual meetings (2005 to 2006) and the 53rd Congress of The Nordic Orthopaedic Federation 2006. We also included handsearch results from the final programmes of SICOT (1996 & 1999) and SICOT/SIROT (2003), the British Orthopaedic Association Congress (2000, 2001, 2002 and 2003), and various issues of Orthopaedic Transactions and supplements of Acta Orthopaedica Scandinavica.

Up to 2007, we scrutinised weekly downloads of "Fracture" articles in new issues of Acta Orthopaedica Scandinavica (subsequently Acta Orthopaedica); American Journal of Orthopedics; Archives of Orthopaedic and Trauma Surgery; Clinical Orthopedics and Related Research; Injury; Journal of the American Academy of Orthopaedic Surgeons; Journal of Arthroplasty; Journal of Bone and Joint Surgery (American and British Volumes); Journal of Orthopedic Trauma; Journal of Trauma; Orthopedics from AMEDEO.

## Data collection and analysis

### Selection of studies

Eligible trials were selected by one author (HH) from the outputs of the search strategies listed above. The initial decisions of trial eligibility were based on citations and, where available, abstracts and indexing terms. Full articles were obtained and, where necessary to ascertain trial methods and status, one author (HH) sent requests for information to trial investigators. Trials appearing to involve random or quasi-random allocation of treatment inventions for proximal humeral fractures in adults were put forward for consideration by all of the review authors listed on the byline for the particular version of the review. Study inclusion was by consensus of all listed review authors.

### Data extraction and management

A data extraction tool was developed, piloted and independently completed by two review authors for each included trial. Details of the study methods, participants, interventions and outcome assessment and results were recorded. Any differences that were clearly not transcription errors were discussed between reviewers. Data management and entry into RevMan was by one author (HH) and checked by another author (BO for this update). When necessary, additional details of trial methodology or data, or both were requested from trialists.

### Assessment of risk of bias in included studies

Risk of bias was independently assessed, without masking of the source and authorship of the trial reports, by at least two authors for newly included trials, and by one author (HH) for trials that had been assessed in previous versions of the review. Between rater and between versions consistency in assessment was checked by HH at data entry. All inter-rater differences were resolved by discussion. We used the tool outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008a). This tool incorporates assessment of randomisation (sequence generation and allocation concealment), blinding (of participants, treatment providers and outcome assessors), completeness of outcome data, selection of outcomes reported and other sources of bias. We considered subjective and functional outcomes (e.g. functional outcomes, pain, clinical outcomes, complications) and 'hard' outcomes (death, reoperation) separately in our assessment of blinding and completeness of outcome data. We assessed two additional sources of bias: bias resulting from imbalances in key baseline characteristics (e.g. age, gender, type of fracture); and performance bias such as resulting from lack of comparability in the experience of care providers.

Additionally, we assessed four other aspects of trial quality and reporting that would help us judge the applicability of the trial findings. The four aspects were: definition of the study population; description of the interventions; definition of primary outcome measures; and length of follow-up.

The 11 aspects of methodological quality assessed in previous versions of the review (before Issue 3, 2010) are shown in Appendix 2.

### Measures of treatment effect

For each trial, risk ratios and 95% confidence intervals were calculated for dichotomous outcomes, and mean differences and 95% confidence intervals were calculated for continuous outcomes.

### Unit of analysis issues

We remained aware of potential unit of analyses issues arising from inclusion of participants with bilateral fractures, and presentation of outcomes, such as total complications, by the number of outcomes rather than participants with these outcomes. There was just one patient with bilateral fractures (Kristiansen 1988) but there was insufficient information to quantify the small difference this would have made to study findings. We avoided the second described unit of analysis problem, mainly by reporting on incidences of individual complications.

### Dealing with missing data

We contacted trialists for missing information, including for denominators and standard deviations. We performed intention-to-treat analyses where possible. We did not impute missing standard deviations.

### Assessment of heterogeneity

We planned to assess heterogeneity for pooled data from comparable trials by visual inspection of the analyses along with consideration of the chi² test for heterogeneity and the I² statistic (Higgins 2003).

### Assessment of reporting biases

There are insufficient data thus far to merit the production of funnel plots to explore publication bias. The search for trials via conference proceedings and trial registration, together with the contacting of authors for information of trial status and progress has provided some insights on unpublished trials, which generally were abandoned because of poor recruitment.

### Data synthesis

It was intended that, where the data allowed, the results of comparable groups of trials would be pooled using both fixed-effect and random-effects models; the selection of the model for presentation was to be determined by the estimation of the extent of the heterogeneity.

### Subgroup analysis and investigation of heterogeneity

We set out a priori two subgroup analyses: by age groups (initially, under versus over 65 years) and by types of fracture (initially, minimally displaced versus displaced based on the Neer classification). To test whether the subgroups are statistically significantly different from one another, we planned to test the interaction using the technique outlined by Altman 2003.

### Sensitivity analysis

We planned sensitivity analyses based on aspects of trial methodology; specifically the risk of bias associated with inadequate concealment of allocation, and to explore the effects of missing data, particularly for dichotomous outcomes.

## RESULTS

### Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies.

#### Results of the search

On extension of the search for trials (the full search was completed in March 2010, but some ongoing trials were identified subsequently), 16 new studies were identified. Of these, one (Fialka 2008) was included, four (Gradl 2009; Mechlenburg 2009; Wan 2005; Yang 2006) were excluded, 10 (Brorson; Guy; Helsinki; HURA; Liverpool; Loma Linda; Pelet; ProCon; ProFHER; Ring) were placed in ongoing trials and one (Luo 2008) awaits assessment. Further reports or retrospective trial registration entries were identified also for several studies in the previous version (Handoll 2003b); this included the published two-year follow-up report for Hodgson 2003. New reports or information resulted in the inclusion of three more trials (Agorastides 2007: former ongoing study Frostick 2003; Fjalestad 2010: former ongoing study Fjalestad 2007; and Lefevre-Colau 2007: formerly Lefevre-Colau 2006, a study awaiting assessment). Further information resulted in the exclusion of two studies (Bing 2002: former ongoing trial Sharma 2000; Dias 2001: former ongoing trial Dias 2001 and study awaiting assessment Der Tavitian 2006).

Summaries of the trial populations of past and the present versions of this review as well as the changes between updates are presented in Appendix 3 .

In all, 16 trials are now included, 11 trials are listed as ongoing, 18 trials are excluded and three are in the Studies awaiting classification.

#### Included studies

All 16 included trials were published as full reports in journals, their availability ranging from 1979 (Lundberg 1979) to 2010 (Fjalestad 2010). Additional information via other publications, conference abstracts, trial registration details and communications from trial investigators were available for six trials (Agorastides 2007; Fjalestad 2010; Hodgson 2003; Hoellen 1997;

Lefevre-Colau 2007; Zyto 1997); these often preceded the availability of the main report. Details of study methods, participants, interventions and outcome measurement for the individual studies are provided in the Characteristics of included studies and summarised below.

### Design

Fifteen trials were randomised clinical trials, although six of these (Hoellen 1997; Kristiansen 1988; Kristiansen 1989; Lundberg 1979; Stableforth 1984; Wirbel 1999) provided no details of their method of randomisation and thus the use of quasi-randomised methods for sequence generation cannot be ruled out. Rommens 1993 was a quasi-randomised trial using alternation for treatment allocation. Livesley 1992 was double-blinded.

### Sample sizes

The 16 included trials involved a total of 801 patients. Study size ranged from 20 participants (Bertoft 1984) to 86 participants ( Hodgson 2003). One trial (Kristiansen 1989) included one person with bilateral fractures; the treatment allocation for this participant was unclear.

### Setting

The 16 included trials were single centre studies conducted in eight different countries: Austria (1 trial); Belgium (1); Denmark (2); France (1); Germany (2); Norway (1); Sweden (4) and UK (4). (Though essentially a single centre trial, the interventions in Hodgson 2003 were undertaken at two centres within an NHS Trust in the UK.) Details of the timing and duration of trial recruitment provided for 12 included trials (*see* the Characteristics of included studies) show Stableforth 1984 to have the earliest start date (1970) and longest period of recruitment (11 years).

### Participants

The majority of participants in each trial were women (70% to 88% of trial population). Most participants were aged 60 and above; two trials (Livesley 1992; Wirbel 1999) included a small number of children. Six trials set lower age limits; the most extreme was Hoellen 1997, where only people who were 65 years or over were included. Zyto 1997 specified that participants should be "elderly". Five trials (Bertoft 1984; Hodgson 2003; Livesley 1992; Lundberg 1979; Revay 1992) included only non or minimally displaced fractures, whereas eight (Agorastides 2007; Fialka 2008; Fjalestad 2010; Hoellen 1997; Kristiansen 1988; Stableforth 1984; Wirbel 1999; Zyto 1997) selected only people with displaced fractures. The majority of fractures were minimally displaced in Kristiansen 1989 and Rommens 1993. Lefevre-Colau 2007 included either minimally displaced or stable impacted fractures. Fractures were graded using the Neer classification system (Neer 1970) in 13 trials, together with the AO classification system in Fialka 2008 and Lefevre-Colau 2007. A modification of the AO classification system as described in Wirbel 1999, and a specific classification system was not referred to in the remaining two trials (Bertoft 1984; Rommens 1993).

### Interventions

Ten trials evaluated conservative treatment, though this was post-operative treatment in two of these. Four trials compared surgical with conservative treatment and two compared two methods of surgery. A list of the comparisons, patient numbers and associated trials grouped according to the main objectives presented in the Objectives is given below.

#### Methods of conservative management (including rehabilitation)

##### *Initial treatment*

- "Immediate" physiotherapy within one week of fracture versus delayed physiotherapy after three weeks of immobilisation in a collar and cuff sling: Hodgson 2003 (86 participants).
- Immobilisation in sling and body bandage for one week versus three weeks: Kristiansen 1989 (85 participants).
- Physiotherapy started within three days of fracture versus delayed physiotherapy after three weeks of immobilisation in a sling: Lefevre-Colau 2007 (74 participants).
- Gilchrist bandage versus "classic" Desault bandage: Rommens 1993 (28 participants).

##### *Continuing management (rehabilitation) after initial conservative treatment involving sling immobilisation*

- Instructed self-physiotherapy versus conventional physiotherapy: Bertoft 1984 (20 participants); Lundberg 1979 (42 participants).
- Swimming pool treatment plus self-training versus self-training alone: Revay 1992 (48 participants).
- Apparatus supplying pulsed electromagnetic field versus dummy apparatus: Livesley 1992 (48 participants).

#### Surgical treatment versus conservative treatment

- Percutaneous reduction and external fixation versus closed manipulation and sling: Kristiansen 1988 (30 participants).
- Internal fixation using surgical tension band or cerclage wiring versus sling: Zyto 1997 (40 participants; 3 more were recorded in Tornkvist 1995).
- Surgery involving open reduction and fixation with an interlocking plate device and metal cerclages versus conservative

treatment starting with immobilisation of the injured arm in a modified Velpeau bandage: Fjalestad 2010 (50 participants).

- Hemi-arthroplasty versus closed manipulation and sling: Stableforth 1984 (32 participants).

#### Different methods of surgical management

- Hemi-arthroplasty versus tension band wiring: Hoellen 1997 (30 participants); an additional nine participants were reported in Holbein 1999.
- Hemiarthroplasty using EPOCA prosthesis versus hemiarthroplasty using HAS prosthesis: Fialka 2008 (40 participants).

#### Continuing management (including rehabilitation) after surgery

- Immobilisation in sling for one week versus three weeks after percutaneous fixation: Wirbel 1999 (77 participants).
- Early active assisted mobilisation (after 2 weeks) versus late mobilisation (after 6 weeks) after cemented hemiarthroplasty: Agorastides 2007 (59 participants)

#### Outcomes

Many trials preceded the availability of validated patient-reported outcome measures (e.g. Oxford Shoulder Score: Dawson 1996) for assessing function. Nonetheless, all trials assessed functioning and pain, but usually reported these as part of a combined overall assessment, such as that of Neer (Neer 1970) and Constant (Constant 1987), that included other measures. Most trials reported on complications. Exceptionally, Fjalestad 2010 reported on costs. Currently, however, only preliminary (one year results) and limited data (none on function) are available for Fjalestad 2010. Livesley 1992 did not provide outcomes split by treatment group.

### Excluded studies

Brief details and reasons for exclusion for 18 studies are given in the Characteristics of excluded studies. It is noteworthy that nine excluded studies were trials that were registered (usually in the now archived National Research Register, UK) but either did not take place (Mechlenburg 2009) or were abandoned due to lack of or poor recruitment (Brownson 2001; Dias 2001; Flannery 2006; Hems 2000; Wallace 2000; Welsh 2000); or not put forward for publication due to compromised methods or data (Bing 2002; Martin 2000).

### Ongoing studies

Details of the 11 ongoing trials are given in the Characteristics of ongoing studies. Only Shah is carried over from the last update. Of particular note are the four ongoing multi-centre trials (Brorson; Guy; ProCon; ProFHER) that compare surgical versus non-surgical intervention in people with displaced fractures.

### Studies awaiting classification

Three studies await classification: see details in the Characteristics of studies awaiting classification. The full report of Luo 2008, which tests acupuncture, is in Chinese and we will seek translation of this article for a future update. As yet, we do not have further details of the other two trials (Parnes 2005; Pullen 2007); both of which were listed in Handoll 2003b.

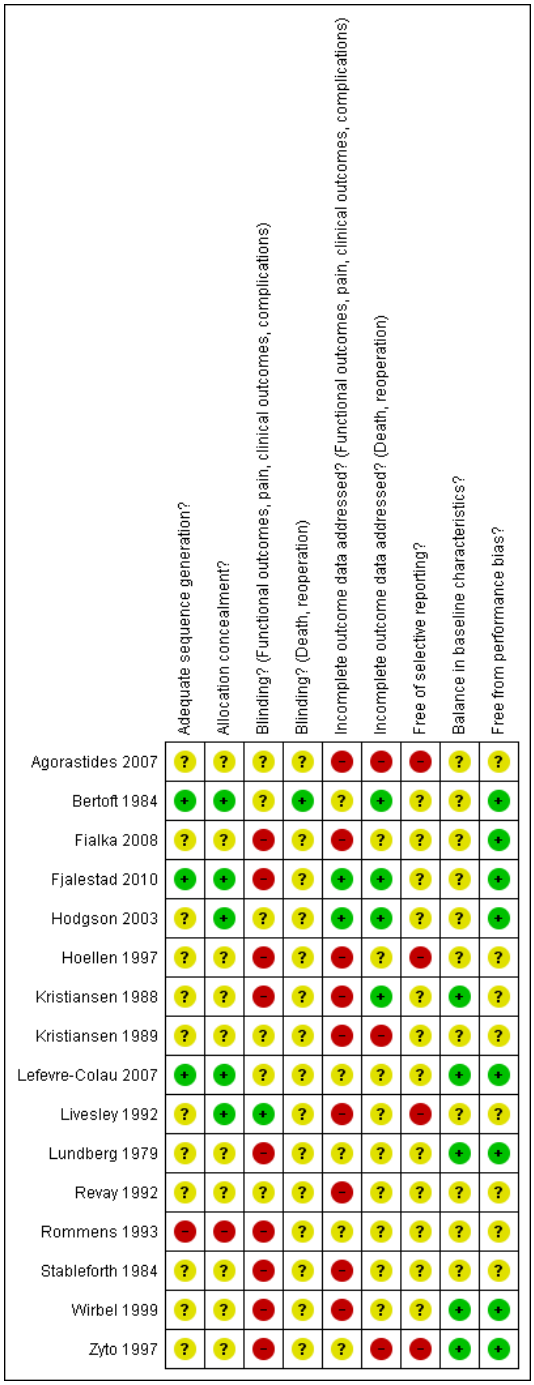
### New studies found at this update

Four trials, including a total of 223 participants, were newly included in this update. Two trials (Agorastides 2007; Lefevre-Colau 2007) evaluated conservative treatment, although this was post-operative treatment in Agorastides 2007. Fjalestad 2010 compared surgical with conservative treatment and Fialka 2008 compared two methods of surgery.

## Risk of bias in included studies

The risk of bias judgements on nine items for the individual trials are summarised in Figure 1 and described in the risk of bias tables in the Characteristics of included studies. A 'Yes' (+) judgement means that the authors considered there was a low risk of bias associated with the item, whereas a 'No' (-) means that there was a high risk of bias. The majority of assessments resulted in an 'Unclear' (?) verdict; this often reflected a lack of information upon which to judge the item. However, lack of information on blinding for functional outcomes was always taken to imply that there was no blinding and rated as a 'No'.

**Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**



### Allocation

Three trials (Bertoft 1984; Fjalestad 2010; Lefevre-Colau 2007) were judged at low risk of selection bias resulting from adequate sequence generation and allocation concealment; and a further two trials (Hodgson 2003; Livesley 1992) also took adequate measures to safeguard allocation concealment. Rommens 1993, a quasi-randomised trial using alternation, was at high risk of selection bias.

### Blinding

A low risk of detection bias for functional outcomes resulting from assessor and participant blinding was judged for Livesley 1992, which used sham controls. While several other trials reported blinded assessors, the lack of reporting of adequate safeguards and the lack of blinding of participants meant that the risk of bias was considered unclear. No blinding was reported in nine trials.

### Incomplete outcome data

Only two trials (Fjalestad 2010; Hodgson 2003) were considered to be at low risk of bias from the incompleteness of data on functional outcomes. Nine trials were deemed at high risk of bias, usually reflecting large losses to follow-up and post-randomisation exclusions.

### Selective reporting

The lack of trial registration details and protocols hindered the appraisal of the risk of bias from selective reporting. Four trials (Agorastides 2007; Hoellen 1997; Livesley 1992; Zyto 1997) were considered at high risk of selective reporting bias.

### Other potential sources of bias

#### Baseline characteristics

No trial was considered at high risk of bias because of confounding resulting from major imbalances in baseline characteristics. However, low risk of bias judgements were given for only five trials (Kristiansen 1988; Lefevre-Colau 2007; Lundberg 1979; Wirbel 1999; Zyto 1997).

#### Care programmes

Risk of performance bias from important differences in care programmes other than the trial interventions or differences in the experience of care providers was judged either low (eight trials) or unclear, usually based on inadequate information, in the other eight trials.

## Effects of interventions

The outcomes reported in the included studies trial reports are listed in the Characteristics of included studies. Where available, outcome data reported at final follow-up for individual trials are presented in the analyses. Pooling of data was not undertaken, even in the those trials reporting a similar comparison, because of clear heterogeneity and incompatible outcome measures.

### Methods of conservative management

#### Initial treatment

Four trials (Hodgson 2003; Kristiansen 1989; Lefevre-Colau 2007; Rommens 1993) reported outcome following initial treatment.

#### Early mobilisation versus delayed mobilisation

Although three trials (Hodgson 2003; Kristiansen 1989; Lefevre-Colau 2007) compared early versus delayed mobilisation, the timing of the start of early mobilisation varied as did the nature and intensity of the physiotherapy provided (notably, the long (two hour) duration of individual physiotherapy sessions of Lefevre-Colau 2007). Lack of comparable outcome measurement and data precluded data pooling and so the results of the individual trials are presented separately below.

Hodgson 2003 compared commencing physiotherapy within one week of fracture versus delayed physiotherapy after three weeks of immobilisation in a collar and cuff sling in 86 people with undisplaced fractures. Trial participants given early physiotherapy attended significantly fewer treatment sessions (*see* Analysis 1.1: mean difference (MD) -5.00 sessions; 95% confidence interval (CI) -8.25 to -1.75) until they and their physiotherapists agreed that independent shoulder function had been achieved. As can be seen in Analysis 1.2, participants of the early group had significantly better health-related quality of life scores at 16 weeks in two dimensions of the SF36 (role limitation physical: MD 22.20, 95% CI 3.82 to 40.58; pain: MD 12.10, 95% CI 3.26 to 20.94). There were no statistically significant differences between the two treatment groups in the other six dimensions (e.g. physical functioning) of the SF36 at 16 weeks, and in all eight dimensions at one

year. Shoulder function, relative to the unaffected shoulder, measured using the Constant score (Constant 1987) was statistically significantly better at eight and 16 weeks (*see* Analysis 1.3: mean difference in ratio affected/unaffected arm 0.16; 95% CI 0.07 to 0.25). Again, the differences at one year, though still favouring the early group, were not statistically significant (MD 0.07, 95% CI -0.03 to 0.17). A report published in 2007 (Hodgson 2007) presented the results for self-reported shoulder disability using the Croft Shoulder Disability Questionnaire (Croft 1994) at one and two years; this report provided identical results to those supplied to us in 2003. These results show a tendency for less disability in the early group at one year, continuing improvement and recovery between one and two years, and also reveal that, overall, a substantial proportion of participants continued to report some or severe disability at two years (*see* Analysis 1.5). Results at two years for eight of the 22 questions of the Croft questionnaire are shown in Analysis 1.6; these are presented to give an indication of the variety of problems experienced by these patients. Only the difference in the numbers reporting pain on movement was statistically significant, but this needs to be viewed in the context of the overall lack of statistically significant differences in other aspects of disability. There were no complications arising from fracture displacement. The only recorded complication in the trial was a frozen shoulder in a participant of the delayed physiotherapy group (*see* Analysis 1.9).

Kristiansen 1989 tested the duration of immobilisation in a sling and body bandage (one week versus three weeks) but provided insufficient follow-up data to allow any test for statistical significance. Additionally, the authors reported that while pain, function and mobility at six months and over were similar in both groups, the patients who started early mobilisation at one week suffered less pain in the first three months than those who kept their bandaging for three weeks. One case of reflex sympathetic dystrophy occurred in each group (*see* Analysis 1.9).

Lefevre-Colau 2007 compared commencing physiotherapy within three days of fracture versus delayed physiotherapy after three weeks of immobilisation in a sling in 74 people with "stable" impacted fractures. Ten trial participants withdrew from the trial because of difficulties in reaching the hospital for treatment. Participants were discharged from physiotherapy at six months. Shoulder function measured using the Constant score was statistically significantly better in the early group at six weeks and three months (*see* Analysis 1.4); the differences at six months and end of treatment, though favouring the early group, were not statistically significant (MD 6.10, 95% CI -0.22 to 12.42). Although the early group had significantly reduced pain compared with the three weeks group by three months, there was no difference at six months (*see* Analysis 1.7). Active range of motion, measured relative to the opposite arm, also did not differ significantly between the two groups at six months (*see* Analysis 1.8). There were no cases of fracture non-union or displacement. One participant of each group received treatment for subacromial impingement. All participants attended at least 70% of the supervised physiotherapy sessions; and very few expressed dissatisfaction with their treatment (*see* Analysis 1.10).

#### Gilchrist versus the Desault bandage

Rommens 1993 compared the use of two types of bandage, the Gilchrist versus the Desault, worn for two to three weeks. More people found the initial application of a Desault bandage uncomfortable and severe skin irritation prompted premature removal of the bandage in two people of this group (*see* Analysis 2.1). Pain during immobilisation was also reported to be greater in the Desault group. Slight displacement of the fracture in the first week was reported in two participants of the Gilchrist group (*see* Analysis 2.2). At fracture consolidation, patients' rating of their assigned bandage was significantly more favourable in the Gilchrist group (*see* Analysis 2.3 "Poor or bad rating by patient at fracture consolidation": 2/14 versus 8/14; risk ratio (RR) 0.25, 95% CI 0.06 to 0.97). However, Rommens 1993 reported that they had found no differences in the end result, either in terms of fracture healing or functional outcome.

#### Continuing management (rehabilitation) after initial conservative treatment involving sling immobilisation

Two small trials compared self-directed treatment following a course of instruction versus conventional physiotherapy during the 12 weeks following trauma (Bertoft 1984; Lundberg 1979). In both trials there were no statistically significant differences between those receiving instruction for exercises at home and those undergoing supervised physiotherapy in any of the outcomes recorded (*see* Analysis 3.1, Analysis 3.2, Analysis 3.3, Analysis 3.4, Analysis 3.5 and Analysis 3.6). It should be noted that since Lundberg 1979 did not report whether there had been any loss to long-term follow-up at an average of 16 months, the results for Neer's score presented in Analysis 3.5 are for illustrative purposes only.

Revay 1992 reported that the addition of supervised exercises in a swimming pool to self-treatment did not enhance long term outcome. Participants of the control group (self-treatment only) were reported as having significantly better functional movements, joint mobility and activities of daily living at two and three month follow-up. However, there were no significant differences at one year. Revay 1992 suggested that those using the pool may have neglected their home exercises, but the authors did not evaluate compliance.

Livesley 1992 reported that there was no difference in outcome between the two groups (pulsed electromagnetic high frequency energy (PHFE) versus placebo) at any stage of the trial, but provided no quantitative data. All trial participants were reported as achieving a "good" result as converse to a "poor" one.

### Surgical treatment versus conservative treatment

Four heterogenous trials evaluated surgical intervention for displaced or high-grade fracture configurations, or both. There were insufficient data for pooling.

Kristiansen 1988 compared percutaneous reduction and external fixation versus closed manipulation and sling immobilisation in 30 people with 31 (displaced) two-, three- or four-part fractures. Fractures were reduced under general anaesthetic in both groups. Treatment failure, defined as a change of method resulting from a poor initial fracture reduction or removal of pins due to infection, occurred in three cases (*see* Analysis 4.1). Overall, the quality of fracture reduction was judged better in the surgical group. Of those followed up to one year, fewer participants of the surgical group had a poor or unsatisfactory rating of function (*see* Analysis 4.2: 3/11 versus 6/10; RR 0.45, 95% CI 0.15 to 1.35). Data provided for the complications of avascular necrosis, non-union and refracture are presented in Analysis 4.3. None of the differences between the two groups for the outcomes shown in the analyses were statistically significant.

Zyto 1997 included only patients with (displaced) three- and four-part fractures in their analyses. Forty patients were allocated either to surgical treatment with cerclage wiring of the displaced fragments, which in some cases was placed around longitudinal wires to obtain tension band fixation, or conservative treatment where the injured arm was supported in a sling. No manipulation of the fracture was attempted in the conservative group. One year later, there were major complications in the surgical group only (*see* Analysis 5.1). At 50 months, only 29 participants were reviewed. Eight of the 11 missing participants had died. Displacement of the greater tuberosity fragment was found in three people treated conservatively and osteoarthritis in two people in each group (*see* Analysis 5.1). There were no statistically significant differences between the two groups at either one or three years in subjective assessment of function (*see* Analysis 5.2). Similarly, there was no difference at three years in the Constant score in terms of the overall functional score (*see* Analysis 5.3: MD -5.00, 95% CI -17.52 to 7.52). Though statistically significant, the clinical relevance of the three point difference in the range of motion component of the Constant score is questionable (*see* Analysis 5.3 for the main components of the Constant score: pain, range of motion, power and activities of daily living).

Fjalestad 2010 also included only patients with (displaced) three- and four-part fractures (AO group B2 or C2). Fifty patients were allocated to either surgery involving open reduction and fixation with an interlocking plate device and metal cerclages to secure the tuberosities or to conservative treatment starting with immobilisation of the injured arm in a modified Velpeau bandage. Self-exercises and instructed physiotherapy started on the third post-operative day for the surgical group and after two weeks in the conservative treatment group. The focus of the first available published report of this trial was primarily on quality of life and costs at one year. A full report of the trial providing two year follow-up and functional outcome data is pending. Treatment failure resulting in a operation occurred in one surgical group participant, who had re-fixation plus bone grafting at six months, and one conservatively treated patient, who had surgery because of fracture redisplacement at two weeks (*see* Analysis 6.1). There were two cases of nonunion in the conservative treatment group, both were without symptoms. Radiographic evaluation revealed more cases of avascular necrosis in the conservative treatment group but the difference between the two groups was not statistically significant (8/23 versus 13/25, RR 0.62, 95% CI 0.31 to 1.22; *see* Analysis 6.1). Two deaths occurred in people with underlying health problems within three months in the surgical group (*see* Analysis 6.2). No differences were found at one year between the two groups in quality of life (*see* Analysis 6.3) or costs (Analysis 6.4 and Analysis 6.5).

Stableforth 1984 included 32 patients with displaced four-part fractures in their comparison of an uncemented Neer prosthesis versus closed manipulation. The forearm and elbow were supported in a sling in both groups, and supervised physiotherapy was provided to all participants between three and six months. Two surgical group participants developed haematomas; one resolved but the other became infected and the prothesis was subsequently removed (*see* Analysis 7.1). One person in each group died before six months from "causes unrelated" to their fracture (*see* Analysis 7.2). By six months, significantly fewer participants of the prosthesis group needed some help with activities of daily living or had died (*see* Analysis 7.3: 2/16 versus 9/16; RR 0.22, 95% CI 0.06 to 0.87). Nearly all trial participants had shoulder pain but significantly fewer in the prosthesis group reported constant pain that impaired sleep or function (*see* Analysis 7.4: 2/15 versus 9/15; RR 0.22, 95% CI 0.06 to 0.86). The categorisation of pain is not clear in the trial report nor whether pain was assessed for all participants. Assuming the latter is the case, then this result is no longer statistically significant when all those with more than occasional pain are included (4/15 versus 9/15; RR 0.44, 95% CI 0.17 to 1.13; NS). Reduced muscle strength and restricted mobility were less frequent in the prosthesis group survivors (*see* Analysis 7.5 and Analysis 7.6).

### Different methods of surgical management

Two trials (Fialka 2008; Hoellen 1997) compared different methods of surgical management.

Hoellen 1997 compared humeral head replacement with an endoprosthesis (internally placed implant) against reduction and stabilisation of the fracture using tension band wiring. All 30 patients reported in Hoellen 1997 had four-part fractures. Patients with three-part fractures were also eligible according to a later report of the trial (Holbein 1999), which reported on 39 patients. However, until we obtain further information from the trialists, we will continue to report the results from Hoellen 1997. In Hoellen 1997, results for only 18 of the 30 trial participants were available at one year. There were no serious peri-operative or post-operative

complications such as pulmonary embolism. No participants of the replacement group required further surgery compared with five participants of the osteosynthesis group (the wires displaced in four participants and the fracture fell apart in one participant): RR 0.09, 95% CI 0.01 to 1.51 (*see* Analysis 8.1 and Analysis 8.2). The mean Constant scores (minus the power component) for the 18 people available at one year follow-up were similar in the two groups (48 versus 49 points out of a maximum of 75). Though we wait on clarification on the inadequately reported results presented in Holbein 1999, these did not appear to differ in a major way from those in Hoellen 1997.

Fialka 2008 compared two types of hemiarthroplasty, the EPOCA prosthesis versus the HAS prosthesis, which differ in a number of ways including the position of fixation of the tuberosities. Of the 40 trial participants, three had died and two were lost to follow-up at one year. Significantly better functional, including range of motion, results at one year were reported for EPOCA prosthesis group. The relative (compared with the patient's uninjured shoulder) individual Constant score results were 70.4% (range 38% to 102%) for the EPOCA group versus 46.2% (range 15% to 80%) for the HAS group (reported P = 0.001). Results for range of motion are shown in Analysis 9.1. Reported complications were two patients with deep infection in the EPOCA group, two patients with persistent pain scheduled for a reoperation in the HAS group (*see* Analysis 9.2), and a periprosthetic fracture that occurred in one of the three patients who had died by one year. Radiological findings, except for heterotropic ossification where there were contradictory data, are shown in Analysis 9.3. These tended to favour the EPOCA prothesis. Fialka 2008 noted some association between the bony resorption of the tuberosities and a decreased Constant outcome score.

### Continuing management (including rehabilitation) after initial surgical treatment

Wirbel 1999 tested the duration of immobilisation (one week versus three weeks) before starting physiotherapy after closed reduction and percutaneous fixation of displaced fractures in 77 patients. Wirbel 1999 reported that there were no statistically significant differences between the two trial groups in their functional results, assessed using the Neer score, at three, six or at an average of 14.2 months. Data provided for unsatisfactory or worse outcome, as defined by the Neer score, at six months are consistent with this claim (*see* Analysis 10.1: 9/32 versus 10/32; RR 0.90, 95% CI 0.42 to 1.92). Premature removal of Kirschner wires because of loosening occurred in the five people in each group (*see* Analysis 10.2); these results, however, were not provided for the whole study population nor was it indicated in which groups the five people who underwent open revision or hemiarthroplasty belonged. Though similar numbers (3 versus 2) of people underwent removal of screws due to subacromial impingement after six months, the numbers of people in each group whose displaced tuberosity fractures were fixed with cannulated screws were not reported. Of the 21 participants followed up more than two years, one developed partial necrosis of the humeral head but was symptom-free and had a full range of motion of his affected shoulder.

Agorastides 2007 reported the findings of early active assisted mobilisation (after 2 weeks) versus late mobilisation (after 6 weeks) after cemented hemiarthroplasty in 49 of the 59 participants recruited in their trial. At one year follow-up, there were no significant differences between the two groups in function as rated by the Oxford shoulder score (*see* Analysis 11.1; mean difference -6.0, 95% CI -16.53 to 4.53; scale was 0 to 100) or the overall Constant score (*see* Analysis 11.2). Both nonunions occurred in the early group but none of the differences between the two groups was statistically significant (*see* Analysis 11.3). The differences between the two groups at one year in elevation and external rotation were neither statistically nor clinically significant (*see* Analysis 11.4).

## DISCUSSION

### Summary of main results

This review, which covers all non-pharmacological treatment and rehabilitation interventions for proximal humeral fractures in adults, now includes 16 single-centre trials with a total of 801 participants. No pooling was possible and the function or pain data available for presentation in the analyses were available for only 469 participants. Thus the main result of this review continues to be the general lack of reliable evidence to inform the treatment of these common injuries.

The comparisons tested by the 16 included trials fell into four main treatment categories.

### Methods of conservative management (including rehabilitation)

Conservative management, generally involving a period of arm immobilisation followed by physiotherapy, of (usually) minimally displaced fractures is the focus of eight trials. There was a general recognition of the impaired function and serious complications, such as complex regional pain syndromes, that could follow a proximal humeral fracture. For example, Bertoft 1984 noted that following injury there is a marked tendency for the capsule of the shoulder joint to contract and for the deltoid muscle to atrophy, leading to stiffness and inferior subluxation of the humeral head respectively.

#### Initial treatment

The extent and duration of initial immobilisation after a fracture are of primary importance. A balance is needed between the advantages of pain relief and avoidance of fracture displacement, and the consequences of immobilisation, notably joint stiffness and muscle atrophy. No data could be pooled from the three heterogeneous trials (Hodgson 2003; Kristiansen 1989; Lefevre-Colau 2007) comparing early versus delayed mobilisation for undisplaced or 'stable' fractures. Nonetheless, early mobilisation appeared to result in earlier recovery and less pain without compromising longer term outcome nor engendering serious complications including fracture displacement. There is limited evidence that the particular type of bandage used neither influences the time to fracture union nor the end functional result, although an arm sling was found to be generally more comfortable than a body bandage (Rommens 1993).

#### Continuing management (rehabilitation) after initial conservative treatment involving sling immobilisation

Two trials (Bertoft 1984; Lundberg 1979) investigated whether patients could undertake their own physiotherapy after receiving appropriate instruction with some monitoring, rather than with full supervision. Conversely, one trial (Revay 1992) studied the supplementation of self-treatment with supervised group training in a swimming pool. Their consensus that patients could generally achieve the desired end result with less supervision is not supported by sufficient evidence.

Livesley 1992 hypothesised that pain was associated with contracture of the capsule of the glenohumeral joint and that pulsed electromagnetic high frequency energy (PHFE) would reduce inflammation and swelling, improving the end functional result. However, the trial failed to provide any quantitative data to support or refute this hypothesis.

### Surgical treatment versus conservative treatment

There were insufficient data for pooling from the four heterogenous trials evaluating surgical intervention for displaced or high-grade fracture configurations, or both.

The additional measures taken to reduce the fracture in the surgical group of Kristiansen 1988 mean that the better anatomical results in the surgical group are to be expected. However, accurate fracture reduction is not invariably associated with a complete recovery of function and conversely excellent shoulder function may be regained after less than optimal fracture reduction. Although Kristiansen 1988 concluded that external fixation gave "better reduction, safer healing and superior function" than closed manipulation, their results were not statistically significant and the small number of patients in this trial at final follow-up were insufficient to demonstrate a better functional outcome following either treatment.

The displacement of fracture fragments in three- and four-part fractures may compromise blood supply and subsequent healing. While two trials related outcome to quality of reduction (Kristiansen 1988; Zyto 1997), both were too small to draw more than very tentative conclusions of effect. Cerclage or tension band fixation using wires was not shown by Zyto 1997 to produce any better long-term shoulder function than simple immobilisation without manipulation. Surgery was also associated with more complications.

Fjalestad 2010 provided limited results at one year for 50 people with three- and four-part fractures treated with either open reduction and fixation with an interlocking plate device and use of metal cerclages versus conservative treatment. Physiotherapy was started earlier in the surgical group (3 days versus 14 days). The focus of the first available published report of this trial was primarily on quality of life and costs at one year; full results at two years are pending. None of the differences in complications, quality of life and costs between the two groups was statistically significant.

Though the findings of Stableforth 1984, which compared hemiarthroplasty with closed reduction for 32 four-part fractures, favoured hemiarthroplasty, the protracted recruitment period and variable follow-up time, along with questions over the method of randomisation and the poorly defined outcome measurement, all limit the confidence with which we can view these results. Interestingly, while the findings confirm the continuing disability following these fractures, Stableforth 1984 did not comment on any treatment including surgery to alleviate subsequent problems such as serious chronic pain.

### Different methods of surgical management

Hoellen 1997 compared humeral head replacement with fracture fixation in 30 people with four-part fractures, but functional outcome data were only available for 18 participants at the one year follow-up. There were no differences between the two groups in the mean Constant scores nor pain. Although all five reoperations occurred in the fixation group, the result was not statistically significant.

Fialka 2008 found significantly better functional, including range of motion, results at one year for the EPOCA prosthesis when compared with the HAS prosthesis in 40 people with four-part fractures. There were no statistically significant differences between the two groups in the incidence of individual adverse events.

### Continuing management (including rehabilitation) after initial surgical treatment

The need for and duration of immobilisation before commencing physiotherapy after surgery for displaced fractures was tested in two small trials, both of which had potentially biased results. Wirbel 1999 provided very limited results on which to judge the claimed lack of difference in outcome following immobilisation for one versus three weeks after surgical fixation. Agorastides 2007 found no statistically significant differences in function (Oxford

shoulder score at one year) and radiological outcome between participants mobilised after two weeks (which was current practice) after hemiarthroplasty versus those mobilised after six weeks. Thus, it is not possible to say whether early mobilisation could destabilise the fracture or hemiarthroplasty or whether it offered any functional advantages.

## Overall completeness and applicability of evidence

To inform consideration of applicability of the evidence from individual trials, we have increased the details given in the Characteristics of included studies on the study populations and interventions. Additionally, Table 1 shows our assessments for each trial of four aspects of relevance to ascertaining external validity: definition of the study population, description of the interventions, definition of primary outcome measures, and length of follow-up. Clearly unhelpful is where there are incomplete descriptions of study inclusion (five trials) and interventions (three trials). Three trials had less than one year follow-up: Lefevre-Colau 2007 (six months), Livesley 1992 (six months) and Rommens 1993 (until fracture consolidation - time unspecified). Despite the claims of longer follow-up, the results seemed to apply to six months at most in Stableforth 1984. In Wirbel 1999, though follow-up of 21 participants was more than two years, the main results applied to the set follow-up at six months.

**Table 1. Assessment of items relating to applicability of trial findings**

| | Clearly defined study population? | Interventions sufficiently described? | Main outcomes sufficiently described? | Appropriate timing of outcome measurement? (Yes = ≥ 1 year) |
|---|---|---|---|---|
| Agorastides 2007 | Partial: exclusions not specified upfront | Yes | Yes | Yes: 1 year |
| Bertoft 1984 | Partial: no exclusion criteria given (e.g. ability to understand instructions for exercises) | Yes | Yes | Yes: 1 year |
| Fialka 2008 | Yes | Yes | Yes | Yes: 1 year |
| Fjalestad 2010 | Yes | Yes | Yes | Yes: 2 years |
| Hoellen 1997 | Yes: but some question over fracture type in that the Holbein 1999 report included 3-part fractures too | Yes | Yes | Yes: 1 year |
| Hodgson 2003 | Yes | Yes | Yes | Yes: 2 years |
| Kristiansen 1988 | Partial: no exclusion criteria given | Partial: incomplete description of timing of sling use and care of external fixator pin sites | Partial: no description of measurement procedures | Yes: 1 year |
| Kristiansen 1989 | Partial: no exclusion criteria given | Partial: although sling and body bandage are common expressions, some variation possible | Partial: no description of measurement procedures | Yes: 24 months |

**Table 1. Assessment of items relating to applicability of trial findings** (*Continued*)

| | | | | |
|---|---|---|---|---|
| Lefevre-Colau 2007 | Yes | Yes | Yes | Partial: 6 months |
| Livesley 1992 | Yes: although this included 4 patients under 20 years with epiphyseal fractures | Yes | Yes | Partial: 6 months |
| Lundberg 1979 | Partial: no exclusion criteria given (e.g. ability to understand instructions for exercises) | Yes | Yes | Yes: 1 year or above (mean: 16 months) |
| Revay 1992 | Yes | Partial: frequency of swimming sessions not stated | Yes | Yes: 1 year |
| Rommens 1993 | Yes: but to note that other fractures including rib (3 participants) were included | Yes | Partial: functional outcome assessment not described (sufficiently) | No: only until fracture consolidation |
| Stableforth 1984 | Yes | Yes | Partial: no description of measurement procedures, incomplete description of pain categories | Partial: up to 6 months, then between 18 months to 12 years. This is too spread out. Most results applied to the 6 month follow-up. |
| Wirbel 1999 | Yes | Yes | Partial: no description of measurement procedures | Partial: between 9 and 36 months; < 1 year in 10 participants. Main results applied to 6 months. |
| Zyto 1997 | Yes | Yes | Yes | Yes: 1 year, and 3 to 5 years |

The measurement of outcome was variable, though generally comprehensive. There was frequent use of non-validated or, at best, partly validated scoring systems such as the Neer (Neer 1970) and Constant (Constant 1987) systems, but also of simple rating systems for individual outcomes. Validated schemes such as the Oxford Shoulder Score (Dawson 1996) and Shoulder Rating Questionnaire (L'Insalata 1997) for subjective assessment of symptoms and function were not available at the time for most of the included trials. Nonetheless, some consideration of interobserver reproducibility and other aspects of validity was evident in the establishment of the Constant score and in two trials (Lundberg 1979; Zyto 1997). Non-validated outcome assessment schemes, often with arbitrary criteria for grading overall outcome (excellent, good, fair, poor), are probably best viewed as 'blunt' and flawed instruments. This needs to be noted when viewing the results of many of the included trials; in particular Kristiansen 1989 whose outcome assessment is almost completely based on the Neer scoring system. More recent trials are generally better in this respect: Agorastides 2007 reports the Oxford Shoulder Score; Fjalestad 2010 recorded American Shoulder and Elbow Surgeons score (data are not available yet); and Hodgson 2003 used of the SF36 health

survey and a validated scheme for self-reported disability resulting from shoulder problems (Croft 1994).

The majority of the trials used Neer's fracture classification (Neer 1970). Problems, such as poor interobserver reproducibility and intraobserver reliability, with the classification of fractures according to the Neer and AO systems have been shown for both radiographs and computerised tomographic scans (Bernstein 1996; Brorson 2008; Sidor 1993; Siebenrock 1993; Sjoden 1997). This variation in the classification of fractures and hence diagnosis needs to be considered when interpreting the results of trials, both in respect to the comparability and composition of the intervention groups and in the applicability of the trial's findings. The limitations of the Neer classification scheme were also demonstrated by the identification of the valgus impacted four-part fracture as a separate category with a lower risk of avascular necrosis (Jakob 1991). Ideally a fracture classification system should act as a guide to treatment as well to enable the comparison of results from studies of patients with similar fracture patterns. However, other factors, such as osteoporotic bone, associated soft tissue injury and the patient's overall health and motivation, will also influence treatment choices and outcome.

While it is possible that all 16 trials are relevant to current practice somewhere in the world, it is likely that some interventions are now rarely used. These include body bandages as tested in Rommens 1993: nowadays it is much more common practice to use either a 'collar and cuff' sling or a 'poly-sling(these incorporate a chest strap that can be passed around the body). Additionally, the applicability of the findings from older trials, such as Stableforth 1984, is potentially less given subsequent changes in practice including the availability of new implants. Notably, there is only one included trial (Fjalestad 2010) that has evaluating the use of locking plates. These are being increasingly used and promoted for these fractures (Thanasas 2009). New materials are also being used, such as the widespread use of non-metallic materials instead of metal wires to achieve 'tension band fixation'.

## Comments on individual comparisons

## Methods of conservative management (including rehabilitation)

### Initial treatment

Though Hodgson 2003 provides strong evidence in favour of early physiotherapy, and avoiding routine immobilisation, in undisplaced two-part fractures, it is still a small study that might be affected by bias, particularly relating to the lack of blinding. A survey sent to senior hospital physiotherapists working directly with orthopaedic patients revealed large variation in rehabilitation, in particular with regards to routine immobilisation, duration of immobilisation and timing of first contact with a physiotherapist, within and between hospitals in the UK (Hodgson 2003a; Hodgson 2006). This points to the need for a similar but larger and preferably multi-centre trial testing the same comparison as Hodgson 2003 to confirm the results of this trial and examine their applicability.

As noted by McKee 2007 in his commentary on Lefevre-Colau 2007, the applicability of this trial is limited by the intensive physiotherapy regimen used in both groups. Both practically and financially the 32 two-hour sessions of physiotherapy may be difficult for patients and health providers; notably, 10 participants withdrew from the trial because of difficulties in attending. In contrast, the mean numbers of treatment sessions in Hodgson 2003 were nine and 14 respectively in the two groups.

### Continuing management (rehabilitation) after initial conservative treatment involving sling immobilisation

Three trials in this category were based in Sweden and possible differences in conventional physiotherapy regimens within and between countries, then and now, need to be considered when considering the application of trial findings. If they work, self-instruction and home-based exercise programmes are attractive for patients and conserve health care resources. There is some evidence from a Cochrane review on fall prevention that elderly people, if well instructed and with intensive support (regular phone calls etc), can maintain a home-based exercise programme (Gillespie 2003; Gillespie 2009). However, there will still be some elderly patients with insufficient understanding or motivation to perform the required exercises.

### Surgical treatment versus conservative treatment

Trials comparing surgical versus non-surgical interventions, or indeed different surgical interventions, risk losing currency as different implants and methods become available and fashionable. Previously (Handoll 2003b), we observed that: "There are no randomised controlled trials comparing other forms of therapy which are now technically easier to perform given the improvements in intra-operative imaging. These include single and multiple, antegrade and retrograde nailing (Lin 1998; Wachtl 2000), external fixation with fine wires coupled to light-weight frames and percutaneous pin fixation of the head to the shaft coupled with tuberosity wiring (Ko 1996)." We observed that: "These may lower the risk of iatrogenic avascular necrosis (Resch 1997). However, aside from the valgus impacted four-part fracture with its reduced risk of avascular necrosis, many surgeons would not consider stabilisation for comminuted fractures and simply proceed to hemiarthroplasty, especially in older people. One key reason for this approach is the general recognition that hemiarthroplasty following failed fixation is technically difficult and the resulting outcome is usually less satisfactory (Naranja 2000; Sonnabend 2002)." However, this is now challenged by the more recent development of locking plating systems, which allow for stronger constructs and fixation of more complex fracture patterns in osteopenic bone with

the potential for less soft-tissue stripping and compromise to the blood supply (Thanasas 2009). In summary, evolving technology (and marketing forces) mitigates against applying the findings of these types of trials. When considering the validity and applicability of surgical trials, account needs to be taken also of fundamental variations in surgical practice, including facilities and operator expertise. In particular, operator expertise and the linked issue of the surgical learning curve, play a pivotal role in the validity and applicability of surgical trial findings. It is this awareness that is behind the pragmatic decision in the ProFHER trial for surgeons to use methods with which they are familiar rather than stipulate the type of surgery.

#### Different methods of surgical management

Both trials comparing different methods of surgery reported results at one year. However, data at a one year follow-up must be considered preliminary results only given that complications such as avascular necrosis and device failure may not become evident until later. Hoellen 1997 considered only one of several shoulder prostheses now available (the prosthesis was cemented in place). Fialka 2008 compared two shoulder prostheses but although the authors ascribed the different functional outcomes to tuberosity fixation, other design differences may account for these results. These include a different stem finish and a more accurate recreation of pre-operative humeral geometry with the EPOCA prosthesis.

#### Continuing management (including rehabilitation) after initial surgical treatment

The need for and duration of immobilisation before commencing physiotherapy after surgical treatment is likely to depend on the method of fixation or type of prosthesis; and also other factors such as bone quality. While neither trial found conclusive evidence for early mobilisation, it can also be observed that the evidence was inconclusive for later mobilisation too.

### Quality of the evidence

The evidence base for this review, formed from 16 small heterogeneous trials, is very limited. The majority of these trials had serious shortcomings and were at high risk of bias that could affect the validity of their findings. These shortcomings include use of quasi-randomised methods for treatment allocation (Rommens 1993), failure to present supportive data for claims of no differences (Livesley 1992), lack of assessor blinding, and incomplete data. The risk of bias resulting from high loss to follow-up or exclusion of participants from the analyses was considered high in nine trials. There is clearly a need for caution in interpreting the results of small trials which demonstrate 'no evidence of an effect' rather than 'evidence of no effect'. Insufficiences in quantity and quality of the evidence preclude the drawing of robust conclusions for any of the comparisons evaluated by the included trials.

The scarcity of the evidence from randomised trials to inform practice for these common fractures is remarkable and depressing. Partly, it appears that a key problem for conducting trials, especially those involving surgery, is patient recruitment as shown by the abandonment of several, including multi-centre, trials as well as the slow and lower-than-planned recruitment in others. However, the outlook is potentially improving with the registration of five ongoing multi-centre trials that are all testing the important question of whether surgery gives better long term functional outcomes compared with conservative treatment. The published protocols for three of these trials (Brorson; ProCon; ProFHER) all show the use of robust methodology required to minimise bias.

### Potential biases in the review process

While our search was comprehensive it is likely that we have failed to identify some randomised trials, particularly those reported only in abstracts or in non-English language publications. We may also have overlooked mixed-population trials that included proximal humeral fractures as a subgroup. However, we are almost certain that we have not overlooked trials that would provide the definitive evidence that could inform practice. It is clear, from the growing awareness and imperative of trial registration, that such trials are now in progress. Systematic processes were undertaken throughout the review.

### Agreements and disagreements with other studies or reviews

Several systematic reviews, covering either all treatment (Lanting 2008), specific interventions (hemiarthroplasty: Kontakis 2008; Nijs 2009) or treatment questions (surgical versus conservative intervention: Nanidis 2010), for proximal humeral fractures have been published since the last update. All four reviews, which included evidence from a broader spectrum of study designs, have noted the limitations in the available evidence and called for well designed prospective, preferably randomised controlled, trials to inform practice.

## AUTHORS' CONCLUSIONS

### Implications for practice

Overall, there is insufficient evidence from randomised controlled trials to determine which interventions are the most appropriate for the management of different types of proximal humeral fracture.

Currently, most undisplaced proximal humeral fractures are treated conservatively. This generally involves a period of immobilisation followed by supervised physiotherapy. There is some good quality but still limited evidence that early physiotherapy, without routine immobilisation, is effective for undisplaced two-part fractures. There is also some limited evidence that short periods of arm immobilisation are acceptable and that, given adequate instruction, some patients may manage their own rehabilitation programme. However, careful selection and long term monitoring procedures should be put in place to check the outcome of these treatments.

Reduction and surgical fixation of displaced fractures attempt to restore the bony anatomy of the joint and hence joint mechanics. However, the very limited evidence available does not confirm that surgery is preferable to conservative treatment and complications associated with surgery need to be considered. Early results also indicate that quality of life and direct and indirect costs may be independent of treatment methods. In some types of severe injury, a hemiarthroplasty may yet turn out to be a better option than fracture fixation. There is insufficient evidence to establish what hemiarthroplasty is best.

There is insufficient evidence to say when to start mobilisation after either surgical fixation or hemiarthroplasty.

### Implications for research

This Cochrane review incorporates evidence from only 16 small single-centre randomised controlled trials of treatment of proximal humeral fractures. There are many issues that have not been addressed. There is a need for better information with regard to the optimal selection, timing and duration of all interventions. In particular, there is a need to determine if a simple undisplaced fracture should be immobilised, and if so, for how long, and the timing, type and extent of physiotherapy required. The urgent need to define more clearly the role and type of surgical intervention in the management of proximal humeral fracture should be addressed upon completion of trials that are currently underway. Any trials must take account of the important issues of method of randomisation, blinding and duration of follow-up. Such trials should use standard and validated outcome measures, including patient assessed functional outcomes, and also assess resource implications. They should also meet the CONSORT criteria for design and reporting of non-pharmacological studies (Boutron 2008).

This Cochrane review should be maintained and updated as further randomised controlled trials become available. The authors would be pleased to receive information about any other randomised controlled trials relating to the treatment of these fractures.

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* *Indicates the major publication for the study*

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies *[ordered by study ID]*

**Agorastides 2007**

| | |
|---|---|
| Methods | Randomised using sequentially numbered sealed envelopes<br>Assessor blinding: stated for Constant Shoulder Assessment and Oxford scores at 6 and 12 months<br>Loss to follow-up at 1 year: 10 (all exclusions: 4 wrong prosthesis; 1 pathological fracture; 1 deep infection requiring further procedure; 2 initial greater tuberosity malpositioning; 2 did not attend follow-up visits) |
| Participants | Royal Liverpool Hospital, Liverpool, UK<br>Period of study recruitment: October 2002 to October 2003<br>59 patients with displaced proximal humeral fractures, 3-part or 4-part or articular fractures who were treated with cemented hemiarthroplasty. Isolated non-pathologic fractures < 6 weeks old. Physiologically old patients with poor bone quality. Informed consent.<br>Exclusion criteria: no extra information<br>Of 49: 39 female, 10 male; mean age 70 years, range 34 to 85 years |
| Interventions | Intervention started post surgery (mean 10 days; range 1 to 30 days after injury)<br>1. Early active assisted mobilisation (after 2 weeks). Arm kept in sling in neutral rotation for 2 weeks; only pendulum and elbow exercises allowed. Between weeks 3 and 6, progressed to active-assisted exercises; from week 7, to active exercises.<br>2. Late mobilisation (after 6 weeks). Arm kept in sling in neutral rotation for 6 weeks; only elbow exercises allowed. From week 7 to week 12, progressed from pendulum to active-assisted exercises; from week 13, to active exercises.<br>Both mobilisation protocols were supervised by a team of specialist shoulder physiotherapists |
| Outcomes | Length of follow-up: 1 year; also assessed at 2 and 6 weeks, and 3 and 6 months (coinciding with outpatient visits)<br>Oxford shoulder score<br>Constant shoulder score (mobility, strength, pain, activities of daily living)<br>Range of motion: elevation, external and internal rotation<br>Complications<br>Radiological assessment: greater tuberosity migration; superior luxation of prosthesis |
| Notes | The early mobilisation regimen represented normal practice at the hospital. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | No description of method: "Patients were randomly allocated" |

**Agorastides 2007** (*Continued*)

| | | |
|---|---|---|
| Allocation concealment? | Unclear | "Randomization took place in the operating theater after the procedure, by use of sequentially numbered, sealed envelopes." |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | "At the 6- and 12-month visits, an independent blinded observer completed the Constant Shoulder Assessment and Oxford scores." However, care providers and participants were not blind to allocation and assessment of complications was not blinded either. |
| Blinding?<br>Death, reoperation | Unclear | No accounting of these, but lack of blinding unlikely to affect reporting of these. |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | No | Incomplete account of participant flow, with exclusion of 10 participants from the analyses. |
| Incomplete outcome data addressed?<br>Death, reoperation | No | No accounting of these outcomes, but incomplete account of participant flow, with exclusion of 10 participants from the analyses. |
| Free of selective reporting? | No | No protocol available. May have been stopped early, greater tuberosity migration not specifically listed in brief trial entry in the National Research Register (UK). |
| Balance in baseline characteristics? | Unclear | Incomplete data to back up claims of lack of baseline differences as these given only for 49 (10 excluded) but a 5 year difference in mean age (72 versus 67 years). |
| Free from performance bias? | Unclear | Although 3 upper limb surgeons performing the operations agreed to the same procedures a different uncemented prosthesis was used in 4 subsequently excluded participants.<br>"Both mobilization protocols were supervised by a team of specialist shoulder physiotherapists." |

**Bertoft 1984**

| | |
|---|---|
| Methods | Use of permutation table, single-blind, independently administered<br>Assessor blinded<br>Loss to follow-up at 1 year: 7/20 (2 excluded) |
| Participants | Central hospital, Vasteras, Sweden<br>Period of study recruitment: not stated<br>20 patients with non or minimally displaced proximal humeral fractures (7 had fracture of the greater tubercle); sling for 10 days.<br>Exclusion criteria: no information<br>17 female, 3 male; mean age 64 years, range 50 to 75 years |
| Interventions | Interventions started 10 to 12 days post injury, after removal of sling.<br>1. Instructed self exercise: patients instructed to train 5 to 10 minutes, 4 to 5 times daily. They had three training sessions (day 1, weeks 3 & 8 post injury)<br>2. Conventional physiotherapy: 9 sessions (average 20 to 30 minutes), 1 to 2 times each week, over 10 to 12 weeks. No thermoelectrotherapy.<br>Assigned: 10/10<br>Completed ( > 1 year): 7/6 |
| Outcomes | Length of follow-up: 1 year; also assessed at 3, 8, 16 & 24 weeks<br>Range of motion: forward flexion (graph), abduction, internal & external rotation<br>Functional movements: placing hand on neck, placing hand on back<br>Pain: when placing hand on neck: combing hair (graph)<br>Isometric muscle strength: vertical & horizontal pushing<br>Change of treatment requested |
| Notes | The 2 excluded participants were in the control group: 1 died and 1 underwent an operation. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Yes | Mention of "permutation table" and "randomized controlled" trial |
| Allocation concealment? | Yes | "A third person was responsible for the randomization procedure and kept the key to the permutation table" |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | "A second physiotherapist examined the patients. She did not know to which group the patient belonged, and the patients were instructed not to tell her." However, there is no guarantee of blinding and, for practical reasons, neither participants nor care provider were blinded |

**Bertoft 1984** (*Continued*)

| | | |
|---|---|---|
| Blinding?<br>Death, reoperation | Yes | Lack of blinding unlikely to affect assessment of these outcomes |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | Participant flow provided but large loss to follow-up (7/20 = 35%). |
| Incomplete outcome data addressed?<br>Death, reoperation | Yes | Participant flow provided |
| Free of selective reporting? | Unclear | Insufficient information to judge this. |
| Balance in baseline characteristics? | Unclear | Incomplete data to back up claims of lack of baseline differences but a 4 year difference in mean age between groups (66 versus 62 years). |
| Free from performance bias? | Yes | No indication of performance bias. |

**Fialka 2008**

| | |
|---|---|
| Methods | Method of randomisation: referral to random list and randomisation timed at surgery<br>Assessor blinding: no<br>Loss to follow-up at 1 year: 5/40 (3 deaths, 2 lost to follow-up) |
| Participants | Vienna General Hospital, Austria<br>Period of study recruitment: not stated - lasted 22 months<br>40 patients with acute 4 part (Neer) proximal humeral fractures (type C: AO/ASIF classification), aged > 50 years, no history of previous problems in either shoulder, informed consent<br>Exclusion criteria: concomitant vascular or neurological injuries of involved limb; prior operative procedures; neurologic or mental disorders; or drug abuse<br>30 female, 10 male; mean age 75 years; of 35: range 56 to 88 years |
| Interventions | Surgery started 7.3 days of injury (0 to 26 days). General anaesthesia used in all cases. Stems were cemented in place and bone grafting was performed using cancellous bone from patient's humeral head.<br>1. Hemiarthroplasty using EPOCA prosthesis (Argomedical). Fixation of tuberosities using wire cables threaded through a medial and lateral hole in the stem.<br>2. Hemiarthroplasty using HAS prosthesis (Stryker). Fixation of tuberosities using transosseous braided sutures tied to lateral fin of the stem.<br>Same general rehabilitation protocol used for both groups: shoulder kept for 2 weeks in immobiliser to prevent active external rotation, passive movement for 15 minutes per day by physiotherapist to avoid contractures and shoulder stiffness. Then, active range of motion increased to horizontal level. Active external rotation initiated after another 2 weeks.<br>Assigned: ?/? |

**Fialka 2008** (*Continued*)

| | |
|---|---|
| | Completed (at 1 year): 18/17 |
| Outcomes | Length of follow-up: 1 year; also assessed at 12 days, 3 & 6 weeks, and 6 months<br>Functional assessment (individual Constant score, where results were relative to patient's unaffected shoulder)<br>Range of motion (active forward flexion, abduction, external rotation)<br>Radiological assessment: resorption of tuberosities, superior migration of prosthesis, anterior subluxations, glenoid erosion, aseptic stem loosening, secondary dislocation of the tuberosities, heterotropic ossification<br>Deep infection<br>Periprosthetic fracture<br>Reoperation & scheduled for reoperation (persistent pain)<br>Mortality |
| Notes | Differences between the two prostheses include the type and position of fixation of the tuberosities and the volume of the stem in the metaphyseal area, thus allowing different amounts of additional (autologous) cancellous bone grafting.<br>The data for heterotropic ossification were contradictory and not used here.<br>Request for information sent to contact trialist on 19 February 2010. |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|
| Adequate sequence generation? | Unclear | "The random list was designed to finally produce 2 groups of equal size." |
| Allocation concealment? | Unclear | "Each surgeon was informed at the beginning of the operation as to which implant had randomly been selected." |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | No | No blinding. |
| Blinding?<br>Death, reoperation | Unclear | Lack of blinding unlikely to affect assessment of these outcomes. Standardisation of assessment. |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | No | The group allocation and baseline data were not provided for 5 participants: 2 lost to follow-up and 3 who had died. Standard deviations not provided. |
| Incomplete outcome data addressed?<br>Death, reoperation | Unclear | Group allocation not provided for those who had died. |
| Free of selective reporting? | Unclear | Insufficient information to judge this. |

**Fialka 2008** (*Continued*)

| | | |
|---|---|---|
| Balance in baseline characteristics? | Unclear | Incomplete baseline data (5 excluded) to confirm baseline comparability of those in analysis. |
| Free from performance bias? | Yes | No indication of performance bias: a "general rehabilitation protocol was used for all patients regardless of the type of implant."; each of the 4 participating surgeons was experienced in joint replacement surgery. |

**Fjalestad 2010**

| | |
|---|---|
| Methods | Method of randomisation: use of computer software by independent hospital statistician; block size 12; use of numbered opaque sealed envelopes<br>Assessor blinding: no, but assessment by two independent physiotherapists<br>Loss to follow-up at 1 year: 2/50 (2 deaths) |
| Participants | Aker University Hospital, Oslo, Norway<br>Period of study recruitment: May 2003 to May 2008<br>50 patients with displaced proximal humeral fractures, AO group B2 or C2 (displaced 3 and 4 part fracture) who were admitted to hospital. Malposition was at least 45° angular deviation in the true frontal (inclination) or transthoracic radiographic projections, regardless of whether the fracture was impacted or not. The greater or lesser tuberosity had to be displaced at least 10 mm. Furthermore, the displacement between the head and metaphyseal/diaphyseal main fragments should not exceed 50% of the diaphyseal diameter. Age 60 years or over. Informed consent. Resident in Oslo.<br>Exclusion criteria: non-Scandinavian ethnicity, previous history of injury or illness of the injured or contralateral shoulder, injury of the other part of the humerus or the contralateral upper extremity, alcohol- or drug abuse, dementia or neurological disease and severe cardiovascular disease that would contraindicate surgery.<br>44 female, 6 male; mean age 73 years, range 60 to 88 years |
| Interventions | Interventions (and randomisation) started after hospital admission.<br>1. Surgery: operation occurred within the first week after admission to hospital. Open reduction and fixation using a minimally open deltopectoral approach with an interlocking plate device (Locking Compression Plate (LCP) of the AO basic type, Synthes, Switzerland) and metal cerclages to secure the tuberosities. Operation was performed under fluoroscopic control. Then immobilisation in a modified Velpeau bandage until self-exercises and instructed physiotherapy was started on the third postoperative day.<br>2. Non operative treatment: immobilisation in a modified Velpeau bandage for 2 weeks before self exercises and instructed physiotherapy started on day 15.<br>The same self-training programme and instructed physiotherapy programme used for both groups, although the conservative treatment group started 12 days later.<br>Assigned: 25/25<br>Completed (at 1 year): 23/25 |

**Fjalestad 2010** (*Continued*)

| | |
|---|---|
| Outcomes | Length of follow up: 2 years<br>Constant shoulder score (both shoulders)<br>ASES (American Shoulder and Elbow Surgeons) questionnaire<br>Quality of life score: Harri Sintonen 15D instrument (sexual function domain not included)<br>Mortality<br>Fixation failure or redisplacement - subsequent operation<br>Radiographic outcomes including avascular necrosis<br>Health economic outcomes, including direct (cost of surgery; cost of hospital stays) and indirect costs (sick leave, family use of time to assist patient)<br>Length of stay in acute hospital and hospital rehabilitation centre |
| Notes | Information on the trial received December 2006 from Dr Tore Fjalestad.<br>Currently only some results for one year follow-up are published. Communication from Dr Tore Fjalestad in April 2010 indicated that the two year follow-up is likely to be finished during 2010. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Yes | "The [randomisation] procedure was designed by the statistician at the hospital research centre using the computer software S-PLUS 6.0 for Windows 2002 ... Randomisation was based on equal blocks of length 12, with the exception of the last one, which was interrupted due to 50 patients." |
| Allocation concealment? | Yes | "Randomisation was performed by means of consecutively numbered and sealed non-translucent envelopes containing each participant's allocation to surgery or to conservative treatment." Independent statistician. |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | No | Two trained physiotherapists performed the 15D interviews. The physiotherapists were not blinded to group assignment. No provider or participant blinding. |
| Blinding?<br>Death, reoperation | Unclear | Lack of blinding unlikely to affect assessment of these outcomes, but may affect decisions for subsequent surgery. |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | Yes | Participant flow diagram provided and intention-to-treat analysis conducted. |

**Fjalestad 2010** (*Continued*)

| | | |
|---|---|---|
| Incomplete outcome data addressed? Death, reoperation | Yes | Participant flow diagram provided and intention-to-treat analysis conducted. |
| Free of selective reporting? | Unclear | Trial registered after completion. Small discrepancies in trial inclusion criteria. |
| Balance in baseline characteristics? | Unclear | Statistically non significant imbalance in gender (5 versus 1 males) and baseline quality of life scores (higher in surgical group). |
| Free from performance bias? | Yes | All the operations were performed by three surgeons experienced in the procedure performed. |

**Hodgson 2003**

| | |
|---|---|
| Methods | Randomised using sequentially numbered sealed envelopes<br>Assessor blinding: yes, on review of patients at home or clinic appointment<br>Loss to follow-up at 1 year: 4 (1 death); at 2 years: 12 (3 deaths) |
| Participants | Royal Hallamshire Hospital, Sheffield, UK<br>Period of study recruitment: November 1998 to April 2000<br>86 patients, over 40 years old, with minimally displaced 2 part fractures (Neer), including isolated fractures of the greater tuberosity<br>Exclusion criteria: inability to understand written or verbal information<br>70 female, 16 male; mean age 70 years |
| Interventions | Intervention started: at arrival at A&E.<br>1. Early physiotherapy (within 1 week of the fracture). Most patients were seen by a physiotherapist at clinic the day after their fracture. Patients received a sling for comfort but were instructed to take their arm out of the sling and to perform gradual, assisted movements of the upper limb.<br>2. Late physiotherapy after 3 weeks of immobilisation in a collar and cuff sling.<br>Both groups received same rehabilitation programme. First 2 weeks: education and instruction for home exercises; weeks 2 to 4: progression to full passive flexion and light functional exercises; week 4: start of progressive functional exercises. Discharge when both patient and physiotherapist thought independent shoulder function was achieved. |
| Outcomes | Length of follow-up: 2 years, also 8 and 16 weeks and 1 year<br>Functional assessment (Constant score)<br>Patients' perceived health status: SF36 (physical function, physical role limitation, pain) ; Croft shoulder disability questionnaire<br>Complications<br>Number of physiotherapy treatment sessions |

**Hodgson 2003** (*Continued*)

| | |
|---|---|
| Notes | Information on this trial received from Mr Hodgson on several occasions. This included draft report of the 2 year follow-up and notice of their plan to extend follow-up to 5 years. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | No details: "using sequentially numbered sealed envelopes we randomly allocated patients" |
| Allocation concealment? | Yes | "using sequentially numbered sealed envelopes we randomly allocated patients". Also from phone conversation (08/08/2001): "physio opened envelopes when details entered on envelope". |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | Blinded assessor of function but patients and care providers were not blinded. |
| Blinding?<br>Death, reoperation | Unclear | Lack of blinding unlikely to affect assessment of these outcomes. |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | Yes | A full account of loss to follow-up provided. While 14% at 2 years (12/86), it was under 5% (4/86) at 1 year. |
| Incomplete outcome data addressed?<br>Death, reoperation | Yes | Participant flow provided. |
| Free of selective reporting? | Unclear | Trial registration was incomplete and differed slightly from final reports. |
| Balance in baseline characteristics? | Unclear | More males in the early mobilisation group (11 versus 5). |
| Free from performance bias? | Yes | Performance bias seemed unlikely. |

**Hoellen 1997**

| | |
|---|---|
| Methods | Randomisation method unknown<br>Assessor blinding: not stated<br>Loss to follow-up at 1 year: 12/30 (3 deaths) |

**Hoellen 1997** (*Continued*)

| | |
|---|---|
| Participants | University Clinic Ulm, Germany<br>Period of study recruitment: 1/12/1994 to 30/06/1996 in Hoellen 1997 report (to 31/08/1998 in Holbein 1999 report)<br>30* patients with 4 part fractures (Neer). *see Notes.<br>Exclusion criteria: age < 65 years, > 14 days since fracture, rheumatoid arthritis, previous shoulder injury, terminally ill<br>24 female, 6 male; mean age 74 years |
| Interventions | Interventions started within 14 days of fracture.<br>1. Hemi-arthroplasty (Global prosthesis, DePuy, US) - cemented<br>2. "Minimal osteosynthesis": tension band wiring - 2 pins + figure of 8 wire<br>All were given low dose heparin for DVT prophylaxis. The same post-operative treatment was used in both groups. A Glichrist bandage was used for temporary rests. Passive moving exercises started from first postoperative day, with active exercises postponed until after 6 weeks. Referral to rehabilitation clinic for 3 to 4 weeks post discharge.<br>Assigned: 15/15<br>Completed (1 year): 9/9 |
| Outcomes | Length of follow-up: 1 year<br>Functional assessment (Constant score)<br>Mobility (component of Constant score)<br>Pain (ditto)<br>Power<br>Haematoma<br>Infection<br>Implant failure<br>Medical complications<br>Re-operation<br>Time on ward<br>Discharge location<br>Mortality |
| Notes | The plan for longer term follow-up was announced in the Hoellen 1997 trial report. Further abstracts and a trial report (Holbein 1999) were identified for the review update (Issue 4, 2003). Holbein 1999 reported on 39 patients (19 versus 20), with 3- and 4-part fractures, 31 (?/?) of whom had been followed up for 1 year and 24 (?/?) for 2 years. Requests (June 2003) for further information, including for denominators, resulted in the discovery that both Dr Holbein and Dr Hoellen were no longer at Ulm. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | No details: prospective randomised trial |
| Allocation concealment? | Unclear | No details: prospective randomised trial |

**Hoellen 1997** (*Continued*)

| | | |
|---|---|---|
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | No | No blinding. |
| Blinding?<br>Death, reoperation | Unclear | Lack of blinding unlikely to affect assessment of these outcomes |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | No | Participant flow provided but large loss to follow-up (12/30 = 40%); and potential exclusions. |
| Incomplete outcome data addressed?<br>Death, reoperation | Unclear | Participant flow provided but large loss to follow-up (12/30 = 40%). Serious outcomes though are less likely to be missed. |
| Free of selective reporting? | No | Insufficient information to judge this but the pragmatic removal of the power component of the Constant score was post hoc. Also unaddressed difference in trial inclusion criteria between the two reports of this trial. |
| Balance in baseline characteristics? | Unclear | No information on baseline characteristics of the two treatment groups but inclusion criteria rule out some confounders. |
| Free from performance bias? | Unclear | Same post-operative treatment but in all there is insufficient information to assess performance bias. |

**Kristiansen 1988**

| | |
|---|---|
| Methods | Method of randomisation: unknown, "randomly selected"<br>Assessor blinding: unlikely<br>Loss to follow-up at 1 year: 10/31 (4 failed to attend, 2 died, 4 excluded) |
| Participants | Rigshospitalet, Copenhagen, Denmark<br>Period of study recruitment: not stated<br>30 patients with 31 displaced 2-, 3- and 4-part proximal humeral fractures (Neer).<br>Exclusion criteria: no information<br>22 female, 9 male; age range 30 to 91 years |
| Interventions | Interventions started: not stated.<br>1. Percutaneous reduction (using Steinmann pin under image intensifier control) and external fixation (2 half pins with continuous threads into humeral head and 2 or 3 pins into the humeral shaft, and neutralising bar applied; Steinmann pin removed)<br>2. Closed manipulation under general anaesthesia & sling<br>Assigned: 15/16 |

**Kristiansen 1988** (*Continued*)

| | |
|---|---|
| | Completed (at 1 year): 11/10 |
| Outcomes | Length of follow-up: 12 months; also assessed at 3 & 6 months<br>'Treatment failure': poor reduction, pin removal due to loosening<br>Non-union<br>Quality of fracture reduction: good, fair, poor<br>Functional overall score: excellent, satisfactory, unsatisfactory, poor. Neer (without anatomical section)<br>Complications: avascular humeral head necrosis, deep infection, radiographic pseudarthrosis, refracture<br>Reoperations<br>Mortality |
| Notes | In both groups, functional exercises were started under instruction during the first week.<br>Excluded participants were: 1 treatment failure (deep infection) in the surgical group; and 2 treatment failures (poor reduction) and 1 refracture in the conservative treatment group. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | No details: "randomly selected for treatment" |
| Allocation concealment? | Unclear | No details: "randomly selected for treatment" |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | No | No blinding reported. |
| Blinding?<br>Death, reoperation | Unclear | Unlikely to be affected by lack of blinding |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | No | Exclusion of data for participants with treatment failure and early refracture from 12 month review. Large loss to follow-up (10/31 = 32%). |
| Incomplete outcome data addressed?<br>Death, reoperation | Yes | Participant flow provided. |
| Free of selective reporting? | Unclear | Insufficient information to judge this. |
| Balance in baseline characteristics? | Yes | No information on the patient with bilateral fractures but a relatively minor unit of analysis issue. |

**Kristiansen 1988** (*Continued*)

| | | |
|---|---|---|
| Free from performance bias? | Unclear | No information on operator competence/ expertise. |

**Kristiansen 1989**

| | |
|---|---|
| Methods | Method of randomisation: unknown<br>Assessor blinding: yes at 2 year follow-up<br>Loss to follow-up at 2 years: 46/85 (18 deaths, 28 non-attenders) |
| Participants | Hvidovre University Hospital, Denmark<br>Period of study recruitment: 1983<br>85 patients with proximal humeral fractures; 74% minimally displaced (Neer).<br>Exclusion criteria: no information<br>60 female, 25 male; median age 72 years (1 week group), 70 years (3 weeks group) |
| Interventions | Interventions started immediately or after closed or open manipulation.<br>1. One week immobilisation in sling and body bandage.<br>2. Three weeks immobilisation in sling and body bandage.<br>At the end of immobilisation, instructions were given to perform Codman's pendulum exercises as well as active movements of the elbow and hand.<br>Assigned: 42/43<br>Completed (at 2 years): 18/21 |
| Outcomes | Length of follow-up: 2 years; also assessed at 1, 3, 6 & 12 months<br>Overall score (Neer without anatomic section)<br>Mobility: overall from Neer score (range of motion: flexion, extension, abduction, internal & external rotation)<br>Function: overall from Neer score (strength, reaching, stability)<br>Pain: overall from Neer score (none to disabling)<br>Reflex sympathetic dystrophy |
| Notes | Post immobilisation for both groups: instructions given for Codman's pendulum exercises as well as active movements of elbow and hand. |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|
| Adequate sequence generation? | Unclear | No details: "Random allocation to immobilization for 1 to 3 weeks was performed" |
| Allocation concealment? | Unclear | No details. |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | Only claimed for outcome assessors at final follow-up: "The 2-year follow-up examination was blind, as the examiners had no knowledge of the period of immobilization." |

**Kristiansen 1989** (*Continued*)

| | | |
|---|---|---|
| Blinding?<br>Death, reoperation | Unclear | No blinding but may not have affected appraisal of mortality (which was not split by treatment group). |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | No | Large loss to follow-up (46/85 = 54%). Numbers given for those available at follow-up but incompletely reported data: only medians. |
| Incomplete outcome data addressed?<br>Death, reoperation | No | Although numbers given for those available at follow-up, only overall mortality data provided (extracted from graph). |
| Free of selective reporting? | Unclear | Insufficient information to judge this. |
| Balance in baseline characteristics? | Unclear | Although there appeared to be comparability between treatment groups in age and gender, the percentage of minimally displaced fractures (79% versus 70%: 33/42 versus 30/43) differed between the two groups and no information was available on the numbers who had open manipulation (thus entailing surgery). |
| Free from performance bias? | Unclear | Lack of information to judge on performance bias. |

**Lefevre-Colau 2007**

| | |
|---|---|
| Methods | Randomised using block randomisation (under supervision of a statistician) and telephone to an independent researcher with patient details.<br>Assessor blinding: yes<br>Loss to follow-up at 6 months: 10 (all had difficulties in travelling to the hospital for scheduled sessions) |
| Participants | Cochlin Hospital, Paris, France<br>Period of study recruitment: October 2002 to March 2005<br>74 patients, over 20 years old, with non-operatively treated impacted ("stable") fractures, including minimally displaced (1-part fracture); 2-part (surgical neck or greater tuberosity (1)); and 3-part (surgical neck and greater tuberosity) (Neer). (AO classification also given). Written consent.<br>Exclusion criteria: pre-existing shoulder pathology, neurological upper limb disorder, indication for shoulder surgery, multiple injuries, high-energy trauma, or difficulties with language or unable to understand rehabilitation programme or other treatment information.<br>54 female, 20 male; mean age 63 years |

| | |
|---|---|
| Interventions | Intervention started with 72 hours after fracture.<br>1. Early mobilisation: active rehabilitation begun within 72 hours of fracture: 2 hour sessions supervised by a physiotherapist, 5 times a week. Progressing from physical techniques to manage pain, then passive motion, performed by physiotherapist, in a) abduction, with arm suspension and patient supine (session 1); passive range of motion in forward elevation with the patient in a lateral supine position (session 2), with addition of external rotation with the patient in a seated position at session 8. After 3 weeks, sessions occurred twice a week without arm suspension. Patients wore a sling between sessions for 4 to 6 weeks, depending on the level of pain. After 6 weeks, active range of motion was begun during weekly sessions. Strengthening began at 3 months in twice-monthly sessions. Patients underwent a total of 32 sessions.<br>2. Usual care, starting with 3 weeks of sling immobilisation. Then 2 hour sessions supervised by a physiotherapist 4 times a week for 4 weeks. Passive mobilisation in all planes without arm suspension was performed by physiotherapist. Patients kept their arm in a sling between sessions for 1 to 3 additional weeks, depending on pain level. Then sessions were scheduled 2 times weekly for 5 weeks. Active range-of-motion exercises began after 6 weeks. After 9 weeks of rehabilitation, sessions occurred twice monthly until 6 months. Each patient underwent a total of 33 sessions.<br>Patients used oral analgesics to manage pain. After 4 to 6 weeks, patients were advised to perform daily exercises at home. Patients were discharged from the study at 6 months. |
| Outcomes | Length of follow-up: 6 months, also 6 weeks and 3 months<br>Functional assessment (Constant score: split into subjective and objective components)<br>Pain<br>Patient satisfaction<br>Range of motion: abduction, anterior elevation, lateral rotation<br>Complications: non-union (0); fracture displacement (0); treatment (injection) for subacromial impingement syndrome<br>Compliance |
| Notes | |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|
| Adequate sequence generation? | Yes | "Block randomization involved choosing randomly from among blocks of lengths 4 and 2 to prevent the risk of predictability." |
| Allocation concealment? | Yes | "After completion of the trial entry details, an independent researcher responsible for treatment allocation was contacted by telephone." |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | "Outcome measures were recorded by two physicians, including one of the authors (F.F.), who were blinded to the treatment |

**Lefevre-Colau 2007** (*Continued*)

| | | |
|---|---|---|
| | | assignments." However, care providers and participants were not blinded to allocation. |
| Blinding?<br>Death, reoperation | Unclear | Not reported. |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | Data were unavailable from 10 participants (5 in each group) who were lost to follow-up because of difficulties in travelling to the hospital. Their characteristics were reported not to differ from those who attended. |
| Incomplete outcome data addressed?<br>Death, reoperation | Unclear | Not reported. |
| Free of selective reporting? | Unclear | Insufficient information to judge this; retrospective trial registration. |
| Balance in baseline characteristics? | Yes | |
| Free from performance bias? | Yes | Rehabilitation was standardised and "delivered by physiotherapists who were experienced in the field". |

**Livesley 1992**

| | |
|---|---|
| Methods | Method of randomisation: unknown, double-blind<br>Assessor blinding: likely as code only broken at end of trial<br>Loss to follow-up at 6 months: 3/48 |
| Participants | Mansfield District General Hospital, Mansfield, UK<br>Period of study recruitment: November 1988 to May 1990<br>48 patients with minimally displaced humeral neck fractures (all Neer Group 1); 4 had epiphyseal fractures<br>Exclusion criteria: able to co-operate with treatment and attend daily therapy for the first 10 working days.<br>37 female, 11 male; age range 11 to 85 years |
| Interventions | Interventions started on average 8.6 days since injury, upon referral to physiotherapy department.<br>1. Pulsed high frequency electromagnetic field ('Curapulse'), 30 minutes/day for first 10 working days. (Intensity setting 3, pulse repetition frequency 35, maximum pulse power 300 watts.)<br>2. Dummy apparatus (deactivated machine).<br>Assigned: 22/26<br>Completed (at 6 months): 21/24 |

**Livesley 1992** (*Continued*)

| | |
|---|---|
| Outcomes | Length of follow-up: 6 months; also assessed at 1 & 2 months<br>No data provided in report<br>Range of movement of glenohumeral & scapulothoracic joints<br>Pain scores, at rest, on movement, analgesia requirement<br>Muscle wasting and strength<br>Overall functional assessment score<br>Subjective opinion of treatment<br>Overall estimation of treatment (a 'good result')<br>Time to discharge |
| Notes | All patients received the same standardised physiotherapy regimen.<br>No data provided in report for comparison between the two interventions. |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|
| Adequate sequence generation? | Unclear | No details provided: "patients were randomized into two groups" |
| Allocation concealment? | Yes | "double-blind", and randomisation code was only broken at end of the trial period to permit analyses |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | Yes | "double-blind", use of sham control |
| Blinding?<br>Death, reoperation | Unclear | No report of these outcomes |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | No | Although loss to follow-up reported, no results were presented for the trial groups. |
| Incomplete outcome data addressed?<br>Death, reoperation | Unclear | No report of these outcomes |
| Free of selective reporting? | No | Results not presented. |
| Balance in baseline characteristics? | Unclear | Baseline comparability. However, although the article claims "patients ... were referred to the physiotherapy department without delay", the ranges for average time from injury to start treatment were 0 to 17 days (active) and 0 to 27 days (sham). |

**Livesley 1992** (*Continued*)

| | | |
|---|---|---|
| Free from performance bias? | Unclear | "Standardized physiotherapy regimen". However, although the article claims "patients ... were referred to the physiotherapy department without delay", the ranges for average time from injury to start treatment were 0 to 17 days (active) and 0 to 27 days (sham). |

**Lundberg 1979**

| | |
|---|---|
| Methods | Method of randomisation: unknown<br>Assessor blinding: no, but mention of independent assessors<br>Loss to follow-up at 3 months: 0/42; not known for final assessment. |
| Participants | Gavle, Sweden<br>Period of study recruitment: not stated<br>42 patients with undisplaced proximal humeral fractures (all Neer Group 1) fixed with a sling; 13 had avulsion of the greater tuberosity.<br>Exclusion criteria: no information<br>37 female, 5 male; mean age 65 years |
| Interventions | Interventions started 7 days post injury, after removal of sling.<br>1. Instructed self exercise: patients instructed to train 5 to 10 minutes, 4 to 5 times daily. They had 3 visits (day 1, and 1 & 3 months) to physiotherapist for instructions and checks. At 1 month, patients were told how to extend their exercises to same level as in physiotherapy group.<br>2. Conventional physiotherapy: 9 visits (average 20 to 30 minutes) between 2 to 3 months; patients encouraged to continue exercise at home. At about 4 weeks, treatment was intensified.<br>Assigned: 20/22<br>Completed (at 3 months): 20/22; (at mean 16 months): ?/? |
| Outcomes | Length of follow-up: > 1 year (mean 16 months); also assessed at 1 & 3 months<br>Range of movement: abduction, shoulder elevation - active & passive<br>Pain (insignificant, moderate, severe), longstanding<br>Lifting power of shoulder<br>Frozen shoulder (secondary)<br>Neer score (at final evaluation) including failure category<br>Hand grip strength |
| Notes | No indication in the report of any loss to follow-up at last follow-up (> 1 year), but cannot be assumed. |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|

**Lundberg 1979** (*Continued*)

| | | |
|---|---|---|
| Adequate sequence generation? | Unclear | No details of method: "In all, 42 patients were randomly assigned into two groups." |
| Allocation concealment? | Unclear | No details of method: "In all, 42 patients were randomly assigned into two groups." |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | No | No blinding, although independent assessment claimed: "Examination was made by physicians and physiotherapists independently at 1 month and 3 months.." |
| Blinding?<br>Death, reoperation | Unclear | No reported. |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | Full data provided for 1 and 3 months follow-up; but denominators not stated for long-term (mean 16 months) follow-up |
| Incomplete outcome data addressed?<br>Death, reoperation | Unclear | Data not reported for these outcomes |
| Free of selective reporting? | Unclear | Insufficient information to judge this. |
| Balance in baseline characteristics? | Yes | No major imbalances in baseline characteristics |
| Free from performance bias? | Yes | No indications of performance bias. |

**Revay 1992**

| | |
|---|---|
| Methods | Randomisation from closed envelopes<br>Assessor blinded<br>Loss to follow-up at 1 year: 1/48 |
| Participants | Danderyd Hospital, Danderyd, Sweden<br>Period of study recruitment: not stated<br>48 patients with 2, 3 or 4 part minimally displaced proximal humeral fractures (< 1 cm or < 45 degrees; Neer Group 1) treated conservatively with sling immobilisation for 1 week.<br>Exclusion criteria: patients with skin diseases and/or chlorine allergy, non-ambulatory<br>39 female, 9 male; mean age 66 years |
| Interventions | Interventions started 5 to 10 days post-injury after removal of sling.<br>1. Swimming pool training (30 minutes each session, up to 20 sessions maximum) in groups (6 to 8 patients) plus instructions for self training (see below).<br>2. Instructions for self-training: exercises to be performed at least 4 times a day for 10 to 15 minutes each time, use of hand on injured side for activities of daily living, advice |

**Revay 1992** (*Continued*)

| | |
|---|---|
| | on relaxation and resting positions.<br>Assigned: 25/23<br>Completed: ?/? |
| Outcomes | Length of follow-up: 1 year; also assessed at 3 weeks, 2 & 3 months<br>Pain (analogue scale)<br>Activities of daily living: subjective assessment of 9 activities each rated on a 5 point scale<br>Functional scale: 6 point scale<br>Joint movement (abduction, flexion, internal rotation) |
| Notes | Means (probably) presented without standard deviations. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | No details: "patients were randomized into two groups" |
| Allocation concealment? | Unclear | Insufficient details of safeguards: "randomized and given instructions in a sealed envelope" |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | "All patients were examined by a physiotherapist who did not know which group each patient belonged to". However, no participant or care provider blinding nor mention of ways to prevent disclosure to assessor. |
| Blinding?<br>Death, reoperation | Unclear | Not reported. |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | No | The treatment group of the participant lost to follow-up was not stated. Standard deviations not provided. Graphs only provided for female participants - denominators not provided for these. |
| Incomplete outcome data addressed?<br>Death, reoperation | Unclear | Not reported. The treatment group of the participant lost to follow-up was not stated. |
| Free of selective reporting? | Unclear | Insufficient information to judge this. |
| Balance in baseline characteristics? | Unclear | Baseline data not provided for gender. |

**Revay 1992** (*Continued*)

| | | |
|---|---|---|
| Free from performance bias? | Unclear | Uncertainty if any compensatory advice given for the control group. |

**Rommens 1993**

| | |
|---|---|
| Methods | Method of randomisation: alternation<br>Assessor blinding: unlikely<br>Loss to follow up at 3 weeks: 0/28 |
| Participants | Leuven University Hospital, Belgium<br>Period of study recruitment: 1991<br>28 patients with acute 2- and 3-part proximal humeral fractures (but most were non or minimally displaced).<br>Exclusion criteria: those indicated for surgical intervention, age < 15 years, with multiple injuries or other fractures at same site<br>22 female, 6 male; mean age 69 years, range 25 to 100 years |
| Interventions | Interventions started immediately.<br>1. Gilchrist bandage, 2-3 weeks. The arm was bandaged with mesh type tubing and held by two slings: one round the shoulder and neck and the other which immobilised the distal part of the upper arm. (Bandage allowed wrist and hand exercises.)<br>2. Desault bandage, 2-3 weeks. Arm was immobilised to the chest using a circular elastic body bandage. (Some had one or more strips of plaster to stop the bandage slipping.)<br>Assigned: 14/14<br>Completed (at fracture consolidation): 14/14 |
| Outcomes | Length of follow-up: until fracture consolidation; also assessed at 1 & 3 weeks<br>Functional results: overall result, no data<br>Pain: patient questionnaire, 0 (none) to 100 (significant) scale<br>Dislocation of fracture<br>Complication: skin irritation<br>Removal of bandage<br>Surgeon assessment of ease of application of bandage<br>Patient assessment of bandage |
| Notes | Two fractures in the Gilchrist group required reduction. Seven participants had other fractures: 3 in group 1 (2 rib, 1 vertebra); 4 in group 2 (1 ankle, 1 hip, 1 rib, 1 vertebra).<br>Trial reports in German; translation obtained. |

***Risk of bias***

| **Item** | **Authors' judgement** | **Description** |
|---|---|---|
| Adequate sequence generation? | No | Quasi-randomised: alternation |
| Allocation concealment? | No | Alternation |

**Rommens 1993** (*Continued*)

| | | |
|---|---|---|
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | No | No mention of blinding |
| Blinding?<br>Death, reoperation | Unclear | Not reported |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | While all participants were followed up and intention-to-treat analyses seemed to have been done, no data on function were presented nor were the criteria for judging fracture consolidation. |
| Incomplete outcome data addressed?<br>Death, reoperation | Unclear | Not reported |
| Free of selective reporting? | Unclear | Insufficient information to judge this. |
| Balance in baseline characteristics? | Unclear | Small discrepancies (e.g. in other injuries or having fracture reduction) can have bigger consequences for small group sizes. |
| Free from performance bias? | Unclear | Differences in care programmes cannot be ruled out. |

**Stableforth 1984**

| | |
|---|---|
| Methods | Method of randomisation: unknown, "randomly selected"<br>Assessor blinding: unlikely<br>Loss to follow-up at 18 months to 12 years: 2/32 (2 deaths) |
| Participants | Bristol Royal Infirmary, Bristol, UK<br>Period of study recruitment: 1970 to 1981<br>32 patients with displaced 4-part proximal humeral fractures (Neer).<br>Exclusion criteria: impacted or minimally displaced fractures<br>25 female, 7 male; mean age 68 years, range 52 to 88 years |
| Interventions | Interventions started: within 5 days for surgery.<br>1. Neer prosthesis, uncemented<br>2. Closed manipulation<br>All placed in sling, mobilisation of hand encouraged, shoulder flexion rotation exercises after 2 to 3 days. Supervised physiotherapy for 3 to 6 months.<br>Assigned: 16/16<br>Completed (at 1 year): 15/15 (but totals given as 16/16 in tables in the trial report) |
| Outcomes | Length of follow-up: stated as 18 months to 12 years; but also assessed regularly up to 6 months<br>Dependent in activities of daily living |

**Stableforth 1984** (*Continued*)

| | |
|---|---|
| | Range of motion (flexion, medial rotation, lateral rotation)<br>Pain<br>Muscle strength (flexion, abduction, lateral rotation)<br>Complications: haematoma, cellulitis, deep sepsis, early shoulder stiffness<br>Mortality |
| Notes | |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | No details: "assigned by pre-arranged random selection" |
| Allocation concealment? | Unclear | No details: "assigned by pre-arranged random selection" |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | No | Not blinded |
| Blinding?<br>Death, reoperation | Unclear | No blinding but may not have affected appraisal of mortality |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | No | Large loss to follow-up (46/85 = 54%). Numbers given for those available at follow-up but incompletely reported data: only medians. |
| Incomplete outcome data addressed?<br>Death, reoperation | Unclear | Slight discrepancy in trial report that 2 deaths are reported, one in each group, but long term denominators are as at baseline. |
| Free of selective reporting? | Unclear | Insufficient information to judge this, but the protracted nature of this trial makes selective reporting more likely. |
| Balance in baseline characteristics? | Unclear | Surgical group on average 4.5 years younger, but uncertainties mainly reflect Inadequate information in terms of other co-morbidities and injuries for this broad category of patients. |
| Free from performance bias? | Unclear | Inadequate information on care programme comparability especially given the protracted nature of the trial recruitment. However, one surgeon operated throughout. |

**Wirbel 1999**

| | |
|---|---|
| Methods | Method of randomisation: unknown, "random allocation"<br>Assessor blinding: unlikely<br>Loss to follow up at 6 months: 13/77; also 14 months (9 to 36 months): 18/77 |
| Participants | University Hospital, Homburg/Saar, Germany<br>Period of study recruitment: January 1995 to March 1998<br>77 patients with displaced (separation exceeds 1 cm; fragment angulation > 30 degrees, or when tuberosity fragment is separated by > 3 mm) subcapital humeral fractures of type A1, A3, B and C1 (modified AO classification) treated by closed reduction and percutaneous fixation.<br>Exclusion criteria: Extensive local skin infection. Impacted fractures of type A2 (treated conservatively). Not fit enough to undergo anaesthesia and X-ray of affected shoulder in anterior-posterior plane. Closed reduction not feasible.<br>54 female, 23 male; mean age 63 years, range 6 to 89 years |
| Interventions | Interventions started post-operatively after percutaneous fixation (Kirschner wires plus in 38 cases, cannulated screws).<br>1. 1 week immobilisation in Gilchrist sling<br>2. 3 weeks immobilisation in Gilchrist sling<br>Active mobilisation of elbow from first post-operative day. Active and passive physiotherapy of the shoulder (optional continuous passive motion) after removal of sling. Removal of Kirschner wires after 4 to 6 weeks, with post-procedure continuation of active exercises.<br>Assigned: 38/39<br>Completed (at 6 months): 32/32 |
| Outcomes | Length of follow-up: 9 to 36 (mean 14 months) months (in 59 participants), but also assessed at 1, 3 and 6 months<br>Neer score<br>Complications: avascular necrosis, local infection/haematoma, premature removal of Kirschner wires, screw removal due to subacromial impingement |
| Notes | Short report (1997) from conference proceedings gave interim results for 51 patients. Full report and some results provided by Dr Wirbel (February 2003).<br>Most of the results given in the trial report were either for the whole study population or split by basic AO fracture type. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | No details: "a random allocation of patients in 2 groups was done" |
| Allocation concealment? | Unclear | No details: "a random allocation of patients in 2 groups was done" |

**Wirbel 1999** (*Continued*)

| | | |
|---|---|---|
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | No | No mention of blinding |
| Blinding?<br>Death, reoperation | Unclear | Not blinded but less likely that these outcomes would be affected. |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | No | Limited data on function using a non-validated assessment instrument with a moderate loss to follow-up at 6 months (17/77 = 17%). |
| Incomplete outcome data addressed?<br>Death, reoperation | Unclear | Incomplete data. Although loss to follow-up reported, reoperations were not sufficiently reported by treatment group. |
| Free of selective reporting? | Unclear | Insufficient information to judge this. |
| Balance in baseline characteristics? | Yes | No indication of any major baseline imbalance. |
| Free from performance bias? | Yes | No indication of performance bias from differences in care programmes. |

**Zyto 1997**

| | |
|---|---|
| Methods | Method of randomisation: sealed envelopes<br>Independent assessor at final follow-up<br>Loss to follow-up at 3 years: 14/43 (8 deaths, 2 could not be traced, 1 hemi-prosthesis, 3 exclusions) |
| Participants | Huddinge University Hospital, Stockholm, Sweden<br>Period of study recruitment: April 1990 to February 1993<br>43 "elderly" patients with proximal humeral fractures (AO classification system: A 8; B 27; C 8) - see notes.<br>In trial report:<br>40 patients with displaced 3- or 4-part fractures (Neer).<br>Exclusion criteria: pathological fracture, high energy trauma, < 30% contact between humeral head and shaft, other fractures, impaired ability of patient to co-operate, relevant concomitant disease<br>35 female, 5 male; mean age 74 years |
| Interventions | Interventions started: surgery within 48 hours.<br>1. Internal fixation (cerclage wiring (8): or surgical tension band (14)) under general anaesthesia. Antibiotic therapy. Physiotherapy.<br>2. Non operative treatment: sling for 7 to 10 days. Then physiotherapy.<br>Assigned: 22/21; (20/20)<br>Completed (50 months): 15/14 |

**Zyto 1997** (*Continued*)

| | |
|---|---|
| Outcomes | Length of follow-up: 3 to 5 years (listed as 50 months in trial report; patient questionnaire, clinical and radiological assessment); also after treatment and at 1 year:<br>Subjective assessment of function including ability to carry 5 kg, sleep on injured side, comb hair, perform personal hygiene<br>Constant score: overall shoulder function and components (pain, power, range of motion, activities of daily living)<br>Complications: deep infection, non-union, pulmonary embolism, avascular necrosis of humeral head<br>Mortality |
| Notes | Both groups had the same physiotherapy regimen.<br><br>Three patients excluded from 1995 data set (Tornkvist 1995) as, on review by Zyto and a radiologist, the patients did not have 3- or 4-part fractures (personal communication). Zyto's response to a letter from H. A. Karladani admits that there may have been some inaccuracy in their classification of the fracture patterns but stressed that the Neer classification system was flawed and that other factors such as osteoporotic bone need to be considered too. |

***Risk of bias***

| Item | Authors' judgement | Description |
|---|---|---|
| Adequate sequence generation? | Unclear | "randomised by sealed envelopes" |
| Allocation concealment? | Unclear | "randomised by sealed envelopes" (at time of admission) No indication of safeguards. |
| Blinding?<br>Functional outcomes, pain, clinical outcomes, complications | No | Some independent assessment by radiographer and potentially by main author but no blinding. |
| Blinding?<br>Death, reoperation | Unclear | No blinding but may not have affected appraisal of mortality (which was not split by treatment group). |
| Incomplete outcome data addressed?<br>Functional outcomes, pain, clinical outcomes, complications | Unclear | Post-randomisation exclusions and moderately large loss to follow-up (14/43 = 32%; (11/40 = 28%)). |
| Incomplete outcome data addressed?<br>Death, reoperation | No | Only whole group data presented for deaths out of 40 participants. |
| Free of selective reporting? | No | Insufficient information to judge this but some post-randomisation exclusions and final follow-up performed by first author who does not appear in the earlier reports |

**Zyto 1997** (*Continued*)

| | | |
|---|---|---|
| | | of the trial. |
| Balance in baseline characteristics? | Yes | No important imbalances in baseline characteristics. |
| Free from performance bias? | Yes | No indications of serious performance bias: surgery performed by orthopaedic specialists who were experienced in the surgical technique. |

AO = Arbeitsgemeinschaft fur Osteosynthesefragen / Association for the Study of Internal Fixation (or ASIF)
AVN = avascular necrosis
A&E = accident and emergency
MI = myocardial infarction
PE = pulmonary embolism

## Characteristics of excluded studies *[ordered by study ID]*

| Study | Reason for exclusion |
|---|---|
| Bing 2002 | This was a randomised clinical trial (sealed envelopes - computer generated sequence - held in a box), recruitment 03/11/1997 to 14/01/1999, that compared Rush pins fixation with Polaris nail fixation of displaced two part fractures of the proximal humerus. Contact with a Dr Sharma in July 2000 revealed 65 of the 80 patients in the trial had reached 2 year follow-up. Abstract by Bing et al published in 2002 indicated 40 patients of whom 30 had been followed-up for one year. Information gained via Alison Armstrong from Grahame Taylor (one of the authors of the Bing abstract) indicated that there were some concerns about the extent of missing data. Both groups had a high reoperation rate to remove metal ware causing impingement. This trial has been excluded because of insufficient data.<br>It seems very likely, based on location and study dates, that the trial registration (Der Tavitian 2006) formerly awaiting classification is for this trial. |
| Bolano 1995 | No proximal humeral fractures in a randomised trial of humeral shaft fracture treatment. |
| Brownson 2001 | This is listed in the National Research Register as a multi-centre randomised trial of the management of displaced surgical neck and displaced shaft fractures of the humerus with the Halder humeral nail. Contact with Mr Brownson revealed this to be part of the trial run from Nottingham (*see* Wallace 2000) which had been abandoned. Mr Brownson indicated that the very specific inclusion criteria (2-part fractures with over 50% displacement) had reduced the potential sample size; patient consent had also been a problem. |
| Chapman 1997 | No proximal humeral fractures in a randomised trial of humeral shaft fracture treatment. |
| Chiu 1997 | No proximal humeral fractures in a quasi-randomised trial of humeral shaft fracture treatment. |
| de Boer 2003 | This is a multi-centre comparative study of locked internal fixators and non-operative treatment. Not randomised. |

(*Continued*)

| | |
|---|---|
| Dias 2001 | Trial abandoned. This randomised trial (random number sheets that are remotely administered) compared hemiarthroplasty versus fixation (generally suture reinforced with wires) versus conservative treatment (manipulation, sling for 2 weeks, then mobilisation) for 3- and 4-part fractures of the proximal humerus. Trial started in 2001, with one year follow-up (outcome was assessed by independent physiotherapists). Aimed for 90 to 100 participants, aged > 45 years. Contact with Alison Armstrong revealed that recruitment stalled at 11 patients (16 refusals) in 2008; centre stopped trial when it became a trial site for the ProFHER trial. |
| Flannery 2006 | This is listed in the National Research Register as a randomised trial comparing conservative treatment and hemiarthroplasty for four-part fractures of the proximal humerus. Contact with Mr Flannery revealed his centre failed to recruit anyone into the trial. Mr Turner, the lead investigator of the multi-centre trial, involving the South Thames Shoulder and Elbow Group, confirmed that the trial was abandoned due to the inability to recruit patients. |
| Gradl 2009 | Prospective study involving 152 patients with unilateral displaced and unstable proximal humeral fractures treated either with an antegrade angular and sliding stable proximal interlocking nail or an angular stable plate. Not a randomised or quasi-randomised trial. |
| Hems 2000 | This is listed in the National Research Register as a randomised trial comparing conservative treatment and the Halder humeral nail for displaced fractures of the surgical neck and shaft of the humerus. Contact with Mr Hems revealed this to be part of the trial run from Nottingham (*see* Wallace 2000). Mr Hems indicated that they had had considerable difficulty in recruiting patients (only those with proximal humeral fractures were eligible in his centre) and had no results. |
| Martin 2000 | Contact with a trialist revealed that due to the discovery of problems with randomisation it was decided not to proceed with publication as the trial results could be compromised. |
| Mechlenburg 2009 | This was originally registered as a randomised controlled trial comparing a plate with a hemiarthroplasty. However, it is now registered as a prospective study of fixation with a Philos plate. Inger Mechlenburg confirmed that no patients had been included in the trial - the trial was abandoned because no funding was obtained. |
| Rodriguez-Merchan 95 | No proximal humeral fractures in a quasi-randomised trial of humeral shaft fracture treatment. |
| Wallace 2000 | This is listed in the National Research Register as a multi-centre randomised trial of the management of displaced surgical neck and displaced shaft fractures of the humerus with the Halder humeral nail. Contact with Prof Wallace's secretary revealed that the study had not gone ahead. The secretary mentioned three other sites (Halifax; Liverpool; and one in Scotland). No reason given. *See* Brownson 2001. |
| Wan 2005 | This is a mixed population trial evaluating additional mobilisation therapy that included other fractures (e.g. clavicular and scapular fractures) as well as proximal humeral fractures. This trial was excluded because separate proximal humeral fracture data were not reported and the contact author is unavailable. |
| Warnecke 1999 | A multicentre prospective study but not a randomised trial. |
| Welsh 2000 | This is listed in the National Research Register as a randomised comparison of operative and non-operative management of proximal humeral fractures. This trial was abandoned due to poor recruitment, mainly due to lack of patient consent. |

(*Continued*)

| | |
|---|---|
| Yang 2006 | Correspondence with the author revealed that this was not a randomised trial. The choice of surgery was dependent on the success of closed reduction. |

## Characteristics of studies awaiting assessment *[ordered by study ID]*

**Luo 2008**

| | |
|---|---|
| Methods | Patients were randomly allocated via a random numbers table. |
| Participants | 60 patients (32 females, 28 males; age range: 39 to 62 years) treated operatively for fracture of the surgical neck of the humerus. |
| Interventions | 1. Acupuncture (electroacupuncture and infrared radiation) plus passive exercise of the shoulder joint<br>2. Exercises only: passive exercise of the shoulder joint followed by active exercises<br>Treatment lasted 1 month. |
| Outcomes | Follow-up: 1 month<br>shoulder pain score (VAS)<br>shoulder joint activity |
| Notes | Trial in Chinese with English abstract. Translation of methods section (1.1) confirmed that this was a randomised trial. |

**Parnes 2005**

| | |
|---|---|
| Methods | Patients were "random selected" for surgery or conservative treatment. Study period: January 1, 2003 and December 31, 2003. |
| Participants | 50 patients (38 females and 12 males) with 3- and 4-part fractures and fracture dislocations of the proximal humerus |
| Interventions | 1. Surgical management (12 closed reduction and external fixation; 13 hemiarthroplasty)<br>2. Non-surgical management |
| Outcomes | Length of follow-up: not stated<br>Constant functional assessment score (with "the limited goals" correction) |
| Notes | So far, we have only found one conference abstract report of this trial. This splits the study population into three groups (2 reflecting the 2 different surgical methods). |

**Pullen 2007**

| | |
|---|---|
| Methods | "randomised". Study period (proposed): 01/09/2005 to 01/09/2007 |
| Participants | 100 patients with 2- or 3-part proximal humeral fractures |
| Interventions | 1. T2 proximal humeral nail<br>2. PHILOS plate system |
| Outcomes | Length of follow-up: 16 weeks |
| Notes | So far, we have not located any other report of this study than the details provided in the National Research Register (UK) by a Trauma and Orthopaedic Registrar. |

## Characteristics of ongoing studies *[ordered by study ID]*

**Brorson**

| | |
|---|---|
| Trial name or title | Effect of osteosynthesis, primary hemiarthroplasty, and non-surgical management for displaced four-part fractures of the proximal humerus in elderly: a multi-centre, randomised clinical trial |
| Methods | Multi-centre, randomised clinical trial (central randomisation unit) |
| Participants | 162 patients with displaced 4-part fractures of the proximal humerus |
| Interventions | 1. Hemiarthroplasty<br>2. Fixed-angle plate osteosynthesis<br>3. Non-surgical treatment |
| Outcomes | Follow-up: 3 years (primary outcome: 1 year)<br>Primary outcome: Constant Disability Scale<br>Secondary outcomes: Oxford Shoulder Score, Short Form-36 |
| Starting date | Start date: April 2009<br>End date: March 2012 (final date for primary outcome measure) |
| Contact information | Dr Stig Brorson<br>Department Orthopaedic Surgery<br>Herlev University Hospital<br>Herlev<br>Denmark<br>DK-2730<br>sbrorson@hotmail.com |
| Notes | Published protocol |

**Guy**

| | |
|---|---|
| Trial name or title | A multicentre prospective randomized control trial on the treatment of three and four part proximal humerus fractures in patients 70 years and older |
| Methods | Randomised controlled trial: "randomly (like flipping a coin)" |
| Participants | 120 patients aged 70 years or over with a 3 or 4 part fracture. |
| Interventions | 1. Open reduction and internal fixation<br>2. Non-operative treatment (reduction and immobilisation) |
| Outcomes | Follow-up: 1 year<br>Primary outcome: patients' functional shoulder scores as measured by the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire<br>Secondary outcomes: functional and mental status instruments (i.e. SF-36/EQ-5D) used to assess the patient's health-related quality of life; re-operation rates; and the time required to return to pre-injury level of independence |
| Starting date | February 2009 (but not recruiting in June 2009 or January 2010)<br>Estimated completion date: April 2011 |
| Contact information | Contact: Raman Johal (raman.johal@vch.ca)<br>Principal investigator: Pierre Guy, University of British Columbia |
| Notes | |

**Helsinki**

| | |
|---|---|
| Trial name or title | Effectiveness and cost-effectiveness of operative and conservative treatment of comminuted fractures of the proximal humerus. A randomised, controlled study. |
| Methods | Randomised single blind (outcomes assessor) |
| Participants | 150 older patients with comminuted, displaced fractures of the proximal humerus.<br>Inclusion Criteria: Age over 65 years; acute trauma with randomisation within 7 days of injury; 3- or 4-part fracture with > 5 mm dislocation of the anatomic neck (AO classification C1-2 for non-luxation fractures; C3 for luxation fractures) |
| Interventions | 1. Philos locking plate: open reduction of the fracture (and GH joint), internal fixation with the Philos locking plate. Tuberculum fragments are sutured to the plate with thick non-absorbable suture.<br>2. Global FX hemiarthroplasty: replacement of the humeral articular head with hemiprosthesis. Tubercles are sutured to the prosthesis with thick nonabsorbable sutures.<br>3. Conservative treatment: immobilisation in a supporting brace for 3 weeks, then increasingly active rehabilitation programme supported by a physiotherapist until 12 weeks of the injury. |
| Outcomes | Follow-up: 24 months<br><br>Primary outcomes: Pain at rest and activity (Numeric Rating Scale), Constant score<br>Secondary outcomes: Simple Shoulder test (SST), Disabilities of the Arm, Shoulder and Hand (DASH), |

**Helsinki** (*Continued*)

| | |
|---|---|
| | quality of life assessment (15D), subjective patient satisfaction, complications and costs. |
| Starting date | June 2010<br>Final follow-up date: June 2014 |
| Contact information | Tuomas Lähdeoja, MD: tuomas.lahdeoja@hus.fi<br>Mika Paavola, MD: mika.paavola@hus.fi<br>Helsinki University, Helsinki, Finland |
| Notes | Study is not yet open for patient recruitment (May 26 2010) |

**HURA**

| | |
|---|---|
| Trial name or title | A randomised clinical trial comparing a lateral minimally invasive approach and the traditional anterior approach for plating of proximal humerus fractures |
| Methods | Randomised, single blind (outcome assessors), clinical trial |
| Participants | 90 patients, with humeral surgical neck fracture, Neer II valgus-type, and Neer III. |
| Interventions | 1. Lateral minimally invasive approach (plate fixation)<br>2. Deltopectoral approach (plate fixation) |
| Outcomes | Follow-up: 3, 6, and 12 weeks, and at 6, 12, 18 and 24 months<br>Primary outcome: Quick DASH<br>Secondary outcomes: SF-12v2 Questionnaire, Constant Shoulder Score, the Patient Scar Assessment Scale, complication rate |
| Starting date | Start date: November 2007<br>End date: January 2012 |
| Contact information | Marie-France Poirer<br>Hopital Sacré-Coeur<br>Montreal<br>Quebec<br>Canada<br>H4J1C5<br>mariefrancepoirier@hotmail.com |
| Notes | |

**Liverpool**

| | |
|---|---|
| Trial name or title | Prospective randomised study of reverse shoulder prosthesis and hemiarthroplasty for elderly patients with proximal humeral fractures |
| Methods | Double blind randomised controlled trial |
| Participants | 120 patients, aged 70 years or over, with shoulder fracture that require arthroplasty |
| Interventions | 1. Reverse shoulder prosthesis<br>2. Hemiarthroplasty |
| Outcomes | Follow-up: 1 year<br>Primary outcomes: Activities of daily living of American Shoulder and Elbow Surgeons (ASES); Simple shoulder test<br>Secondary outcomes: 36-item Short Form health survey (SF-36); University of California and Los Angeles (UCLA) scores; radiological outcome |
| Starting date | Listed start date: 01/06/2007 |
| Contact information | Mr Matthew Smith<br>Orthopaedic and Trauma Consultant<br>Royal Liverpool and Broadgreen University Hospitals<br>Prescot Street<br>Liverpool<br>L7 8XP<br>United Kingdom<br>Matthew.Smith@rlbuht.nhs.uk |
| Notes | This trial was listed under Mr C Sinopidis, who has now left this hospital. As of 23 June 2010, this trial had not started (Stephen Brealey, personal communication). |

**Loma Linda**

| | |
|---|---|
| Trial name or title | Clinical outcome comparison between medial and lateral offset reverse shoulder arthroplasty |
| Methods | Randomised single blinded trial |
| Participants | 40 patients aged between the ages of 50 and 95 years of age who are a candidate for a reverse shoulder arthroplasty. This includes patients with rotator cuff tear arthroplasty, irreparable rotator cuff tears, significant proximal humerus fractures and malunions, and chronic proximal humerus dislocators. |
| Interventions | Tornier Reversed shoulder arthroplasty:<br>1. Medial offset design<br>2. Lateral offset design |
| Outcomes | Follow-up: 2 years<br>Shoulder functional score<br>Pain scores<br>Radiological outcomes |

**Loma Linda** (*Continued*)

| | |
|---|---|
| Starting date | May 2010 |
| Contact information | Wesley Phipatanakul, MD<br>wphip@hotmail.com<br>Principal investigator: Montri D Wongworawat, MD,<br>Loma Linda University Health Department of Orthopaedic Surgery, Loma Linda<br>Californa 92354<br>USA |
| Notes | The future inclusion of this mixed population trial will depend on the numbers of participants with proximal humeral fractures. |

**Pelet**

| | |
|---|---|
| Trial name or title | Effectiveness of intensive rehabilitation on shoulder function after a fracture of the proximal humerus treated by locked plate. A prospective randomized study |
| Methods | Randomised clinical trial |
| Participants | 80 patients aged over 18 years treated by PHILOS locked plate system for unstable closed fracture of the proximal humerus (two-part and three-part fractures according to the Neer classification) within 7 days on injury. |
| Interventions | 1. Early and intensive exercise programme<br>A thoraco brachial brace will be worn for 48 hours following the surgery and then removed for the remainder of treatment. Patients will then start the intensive rehabilitation programme without physical therapy. The exercise programme will be provided to the patient. The exercises consist of active and active assisted movements of the shoulder for a period of six weeks, limiting external rotation to 0°. Patients are encouraged to use their affected limb for daily activities. Strengthening exercises are started the 6th week following surgery and the full programme will be completed three months after surgery. Patients who wish can then continue their rehabilitation with a physiotherapist. The patient will complete a daily diary to validate the frequency and intensity of the exercises.<br>versus<br>1. Standard rehabilitation programme<br>The patient will wear the thoraco brachial brace for a period of four weeks following the surgery. It may be taken off for hygiene purposes and dressing up. After the four weeks, the patient will take the brace off permanently and begins an exercise programme, writing down the frequency and intensity of the exercises. Physiotherapy is allowed for the remaining part of the three months rehabilitation programme. |
| Outcomes | Length of follow-up: 12 months<br>Primary outcome: Constant score (adjusted for age) at 6 months. A difference of 10 points is considered significant (standard deviation of 15 points).<br>Secondary outcomes: Reoperation, redisplacement, Constant score at 12 months, Dash, return to professional activities, pain, range of motion |
| Starting date | December 2009<br>Final follow-up date: December 2012 |

**Pelet** (*Continued*)

| | |
|---|---|
| Contact information | Hélène Côté, Reg. Nurse: helco3@hotmail.com<br>Stéphane Pelet, MD, PhD: spelet01@hotmail.com<br>Hopital de l'Enfant-Jésus, Canada |
| Notes | |

**ProCon**

| | |
|---|---|
| Trial name or title | Primary hemiarthroplasty versus conservative treatment for comminuted fractures of the proximal humerus in the elderly (ProCon) - a multicenter randomized trial |
| Methods | Randomised trial: "variable block randomisation will be accomplished via a trial website" |
| Participants | Patients (65 years or older) with a comminuted proximal humeral fracture.<br>80 patients (65 years or older) with a comminuted proximal humeral fracture: three-part (Hertel classification type 9, 10, 11), four-part (Hertel type 12), anatomical neck (Hertel type 2), or split-head fractures of the humeral head |
| Interventions | 1. Hemiarthroplasty (Affinis® Fracture shoulder endoprosthesis)<br>2. Conservative treatment (collar and cuff for three weeks) |
| Outcomes | Follow-up: 1, 3 and 6 weeks, and 3, 6, 12 and 24 months<br>Primary outcome (Constant Score) and secondary outcomes (DASH, pain, radiographic healing, secondary intervention rates, complication rates, mortality rates, SF-36, and EQ-5D)<br>Costs for (in)formal healthcare consumption |
| Starting date | Start date: 15 June 2009<br>Planned end date: 31 December 2013 |
| Contact information | Dennis Den Hartog<br>Department of Surgery-Traumatology<br>Erasmus MC<br>University Medical Center<br>Rotterdam<br>P.O. Box 2040<br>3000 CA Rotterdam<br>The Netherlands<br>d.denhartog@erasmusmc.nl |
| Notes | Published protocol |

**ProFHER**

| | |
|---|---|
| Trial name or title | Pragmatic multi-centre randomised trial of surgical versus non-surgical treatment for proximal fracture of the humerus in adults |
| Methods | Multi-centre randomised controlled trial |
| Participants | 250 patients, aged 16 or above, presenting to the participating trauma centre within 3 weeks of their injury with a radiologically confirmed displaced fracture of the proximal humerus involving the surgical neck |
| Interventions | 1. Surgery (fixation or joint replacement)<br>2. Non-surgical management (sling immobilisation) |
| Outcomes | Follow-up: 6, 12 and 24 months<br>Primary outcome: Oxford Shoulder Score (12-item condition-specific questionnaire providing a total score based on the person's subjective assessment of pain and activities of daily living impairment) assessed at 6, 12 and 24 months via postal questionnaire.<br>Secondary outcomes: 12-item short form health survey (SF-12) and Euroqol (EQ-5D) for general health status data (at 6, 12 and 24 months); complications, including surgical complications (wound infection, implant failure, shoulder dislocation, septicaemia); early medical complications, i.e. chest infection, confirmed myocardial infarction or stroke, treated deep vein thrombosis and pulmonary embolism; mortality; subsequent referral for operation or substantive treatment; data for economic evaluation: NHS and societal costs |
| Starting date | Start date: 1/10/2009<br>End date:30/09/2012 |
| Contact information | Prof Amar Rangan<br>Consultant Orthopaedic Surgeon<br>The James Cook University Hospital<br>Marton Road<br>Middlesbrough<br>TS4 3BW<br>United Kingdom<br>amar.rangan@stees.nhs.uk |
| Notes | Published protocol |

**Ring**

| | |
|---|---|
| Trial name or title | Early vs delayed physical therapy (exercises) for non-operatively-treated proximal humerus fractures: a prospective randomized trial |
| Methods | Randomised trial |
| Participants | 60 patients, aged 18 years or over, with non-operatively treated proximal humeral fractures |
| Interventions | 1. Physical therapy started immediately after diagnosis of injury<br>2. Physical therapy delayed until 3 weeks after diagnosis of injury |

**Ring** (*Continued*)

| | |
|---|---|
| Outcomes | Follow-up: 6 months<br>Primary outcome: shoulder flexion<br>Secondary outcomes: shoulder pain Likert scores; external and internal rotation; abduction; DASH and Constant scores |
| Starting date | Start date: February 2005<br>End date: December 2010 |
| Contact information | Dr David Ring<br>Massachusetts General Hospital<br>Boston<br>Massachusetts<br>USA<br>dring@partners.org |
| Notes | |

**Shah**

| | |
|---|---|
| Trial name or title | Shoulder function following four part fractures of proximal humerus: A prospective randomised trial for treatment of four part fractures of proximal humerus - conservative vs hemiarthroplasty |
| Methods | Randomised trial |
| Participants | 200 patients (planned) with 4 part fractures of the proximal humerus |
| Interventions | 1. Hemiarthroplasty<br>2. Conservative treatment |
| Outcomes | Follow-up: 1 year<br>Constant-Murley shoulder score and Oxford Shoulder score |
| Starting date | Start date: 01/01/2003<br>End date: 01/02/2005 |
| Contact information | Mr N Shah<br>Orthopaedic Department<br>Oldchurch Hospital<br>Waterloo Road<br>Romford<br>Essex<br>RM7 0BE<br>Tel: +44 1708 516010<br>Fax: +44 1708 708041 |
| Notes | Listed in the NRR as a multi-centre trial: no details received of the other centres in the limited further information received from Mr Shah in April 2003.<br>Request for further information sent 13/11/06. |

AO = Arbeitsgemeinschaft fur Osteosynthesefragen / Association for the Study of Internal Fixation (or ASIF)
LCP = Locking compression plate
NRR = National Research Register

## DATA AND ANALYSES

**Comparison 1. Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Number of treatment sessions | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 2 SF-36 scores: pain & physical dimensions | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 2.1 Physical functioning (0-100: excellent) at 16 weeks | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 2.2 Physical functioning (0-100: excellent) at 1 year | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 2.3 Role limitation physical (0-100: none) at 16 weeks | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 2.4 Role limitation physical (0-100: none) at 1 year | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 2.5 Pain (0-100: none) at 16 weeks | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 2.6 Pain (0-100: none) at 1 year | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3 Constant shoulder score (ratio of affected/unaffected arm) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 3.1 8 weeks | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3.2 16 weeks | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3.3 1 year | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 4 Constant shoulder score (0 to 100: best) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 4.1 6 weeks | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 4.2 3 months | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 4.3 6 months | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 4.4 6 months: subjective assessment (0 to 35: best) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 4.5 6 months: objective assessment range of motion and strength (0 to 65: best) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 5 Shoulder disability: Croft Shoulder Disability Score | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 5.1 Disability (1 or more problems) at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5.2 Severe disability (5 or more problems) at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5.3 Disability (1 or more problems) at 2 years | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5.4 Severe disability (5 or more problems) at 2 years | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6 Croft shoulder disability score: individual problems at 2 years | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |

| | | | |
|---|---|---|---|
| 6.1 Pain on movement | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6.2 Bathing difficulties | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6.3 Change position at night more often | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6.4 Disturbed sleep | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6.5 No active pastimes or usual physical recreation | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6.6 Lifting problems | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6.7 Help needed | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6.8 More accidents (e.g. dropping things) | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 7 Changes in pain intensity (mm) from baseline: 100 mm visual analogue scale (positive change = less pain) | 1 | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 7.1 At 6 weeks | 1 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7.2 At 3 months | 1 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 7.3 At 6 months | 1 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8 Range of motion at 6 months (degrees): difference between two shoulders | 1 | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 8.1 Abduction | 1 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.2 Anterior elevation | 1 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 8.3 Lateral rotation | 1 | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 9 Complications | 3 | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 9.1 Frozen shoulder | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 9.2 Fracture displacement | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 9.3 Non-union | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 9.4 Reflex sympathetic dystrophy | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 9.5 Treated (injection) subacromial impingement | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 10 Patient dissatisfied with treatment | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |

**Comparison 2. Gilchrist bandage versus 'Classic' Desault bandage**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Problems with bandages | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 1.1 Application of bandage was uncomfortable | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.2 Premature bandage removal | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2 Fracture displacement by 3 weeks | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |

| | | | |
|---|---|---|---|
| 3 Poor or bad rating by patient at fracture consolidation | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |

**Comparison 3. Instructed self physiotherapy versus conventional physiotherapy**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Pain at one year (scale 0 to 8: maximum pain) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 2 Severe or moderate pain at 3 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 3 Requested change of therapy | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 4 Complications (frozen shoulder: 1 v 2; unexplained prolonged pain: 0 v 1) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 5 Neer's rating (0 to 100: best) at mean 16 months (exploratory analysis) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 6 Active gleno-humeral elevation (degrees) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |

**Comparison 4. Reduction and external fixation versus closed reduction**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Treatment failure by 1 month | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 1.1 Treatment failure | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.2 Poor immediate reduction | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.3 Infection resulting in removal of pins | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2 Poor or unsatisfactory function at 1 year (Neer rating) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 3 Complications | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 3.1 Avascular necrosis at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.2 Non-union | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.3 Refracture | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

**Comparison 5. Cerclage or tension band wiring versus conservative treatment (displaced 3 and 4 part fractures)**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Complications | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 1.1 Infection at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.2 Avascular necrosis at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.3 Non union at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.4 Wire penetration at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.5 Osteoarthritis at 50 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.6 Tuberosity displacement at 50 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2 Activities of dailiy living | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 2.1 Unable to manage personal hygiene at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.2 Unable to comb hair at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.3 Unable to sleep on fractured side at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.4 Unable to carry 5 kg at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.5 Unable to manage personal hygiene at 50 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.6 Unable to comb hair at 50 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.7 Unable to sleep on fractured side at 50 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.8 Unable to carry 5 kg at 50 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3 Constant score at 50 months: overall and components | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 3.1 Overall score (0-100: best score) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3.2 Pain (maximum score 15) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3.3 Range of motion (maximum score 40) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3.4 Power (maximum score 25) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3.5 Activities of daily living (maximum score 20) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |

**Comparison 6. Plating plus cerclage versus conservative treatment (displaced 3 and 4 part fractures)**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Complications | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 1.1 Redisplacement resulting in an operation | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.2 Fixation failure resulting in an operation | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.3 Non union at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 1.4 Avascular necrosis at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2 Mortality at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 3 Quality of life assessment | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 3.1 15D at 3 months (0: death; 1: perfect health) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3.2 15D at 6 months | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3.3 15D at 12 months | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3.4 number of QALYs at 1 year | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3.5 numbers of QALYs at 1 year (- deaths) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 4 Costs at 1 year (Euros in 2005) | | | Other data | No numeric data |
| 5 Total costs including indirect costs (Euros) at 1 year | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |

**Comparison 7. Hemi-arthroplasty versus closed reduction (4 part fractures)**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Deep infection | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 2 Dead at 6 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 3 Dependent in activities of daily living (or dead) at 6 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 4 Constant (often severe) pain at 6 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 5 Failure to recover 75% muscle power relative to other arm (survivors) at 6 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 5.1 Flexion | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5.2 Abduction | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 5.3 Lateral rotation | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6 Range of movement impairments in survivors at 6 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 6.1 Flexion < 45 degrees | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

| | | | |
|---|---|---|---|
| 6.2 Unable to place thumb on mid spine (T12) | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 6.3 Lateral rotation < 5 degrees | 1 | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

**Comparison 8. Hemi-arthroplasty versus tension band wiring (4 part fractures)**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Re-operation at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 2 Implant removal at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 3 Pain at 1 year | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |

**Comparison 9. Hemiarthoplasty: EPOCA prosthesis versus HAS prosthesis**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Range of motion results at one year (degrees) | | | Other data | No numeric data |
| 2 Complications | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 2.1 Deep infection | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 2.2 Persistent pain - scheduled for reoperation | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3 Radiological assessment | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 3.1 Resorption of tuberosities | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.2 Secondary dislocation of tuberosities | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.3 Superior migration of prosthesis | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.4 Anterior subluxations | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.5 Glenoid erosion | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.6 Aseptic loosening of stem | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |

**Comparison 10. Post-operative (percutaneous fixation) immobilisation for 1 week versus 3 weeks**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Neer score ≤ 80 points (unsatisfactory or failure) at 6 months | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 2 Premature removal of Kirschner wires | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |

**Comparison 11. Post-operative (hemiarthroplasty) mobilisation: early (2 weeks immobilisation) versus late (6 weeks)**

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|---|---|---|---|
| 1 Oxford Shoulder Score at 1 year (adjusted: 0 to 100 best) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 2 Constant shoulder score (at 1 year) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 2.1 Overall score (0 to 100: best) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 2.2 Pain component (0 to 15: best)) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 2.3 Activities of daily living component (0 to 25: best) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 2.4 Mobility component (0 to 40: best) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 2.5 Strength component (0 to 25: best) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 3 Radiological assessment | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Totals not selected |
| 3.1 Nonunion (with bone resorption) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.2 Malunion | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.3 Greater tuberosity migration (all had severe pain at 6 & 12 months) | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 3.4 Superior luxation of prosthesis | 1 | | Risk Ratio (M-H, Fixed, 95% CI) | Not estimable |
| 4 Range of motion at 1 year | 1 | | Mean Difference (IV, Fixed, 95% CI) | Totals not selected |
| 4.1 Elevation (degrees) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |
| 4.2 External rotation (degrees) | 1 | | Mean Difference (IV, Fixed, 95% CI) | Not estimable |

### Analysis 1.1. Comparison 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks, Outcome 1 Number of treatment sessions.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks

Outcome: 1 Number of treatment sessions

| Study or subgroup | Early (≤ 1 week) N | Mean(SD) | 3 weeks N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| Hodgson 2003 | 44 | 9 (6) | 42 | 14 (9) | | -5.00 [ -8.25, -1.75 ] |

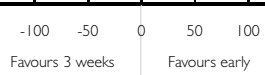

### Analysis 1.2. Comparison 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks, Outcome 2 SF-36 scores: pain & physical dimensions.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks

Outcome: 2 SF-36 scores: pain % physical dimensions

| Study or subgroup | Early (≤ 1 week) N | Mean(SD) | 3 weeks N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Physical functioning (0-100: excellent) at 16 weeks | | | | | | |
| Hodgson 2003 | 42 | 69.9 (25.1) | 39 | 69.2 (23.6) | | 0.70 [ -9.91, 11.31 ] |
| 2 Physical functioning (0-100: excellent) at 1 year | | | | | | |
| Hodgson 2003 | 40 | 65.4 (31.3) | 40 | 68.4 (30.2) | | -3.00 [ -16.48, 10.48 ] |
| 3 Role limitation physical (0-100: none) at 16 weeks | | | | | | |
| Hodgson 2003 | 42 | 61.9 (43.6) | 39 | 39.7 (40.8) | | 22.20 [ 3.82, 40.58 ] |
| 4 Role limitation physical (0-100: none) at 1 year | | | | | | |
| Hodgson 2003 | 40 | 60 (44.1) | 40 | 54.4 (44.2) | | 5.60 [ -13.75, 24.95 ] |
| 5 Pain (0-100: none) at 16 weeks | | | | | | |
| Hodgson 2003 | 42 | 72 (20.6) | 39 | 59.9 (20) | | 12.10 [ 3.26, 20.94 ] |
| 6 Pain (0-100: none) at 1 year | | | | | | |
| Hodgson 2003 | 40 | 69.2 (27.2) | 40 | 65.6 (26.6) | | 3.60 [ -8.19, 15.39 ] |



## Analysis 1.3. Comparison 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks, Outcome 3 Constant shoulder score (ratio of affected/unaffected arm).

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks

Outcome: 3 Constant shoulder score (ratio of affected/unaffected arm)

| Study or subgroup | Early (≤ 1 week) N | Mean(SD) | 3 weeks N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 8 weeks | | | | | | |
| Hodgson 2003 | 43 | 0.57 (0.26) | 40 | 0.39 (0.19) | | 0.18 [ 0.08, 0.28 ] |
| 2 16 weeks | | | | | | |
| Hodgson 2003 | 42 | 0.7 (0.21) | 40 | 0.54 (0.2) | | 0.16 [ 0.07, 0.25 ] |
| 3 1 year | | | | | | |
| Hodgson 2003 | 41 | 0.82 (0.23) | 41 | 0.75 (0.25) | | 0.07 [ -0.03, 0.17 ] |

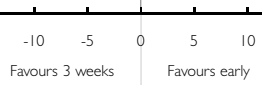
## Analysis 1.4. Comparison 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks, Outcome 4 Constant shoulder score (0 to 100: best).

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks

Outcome: 4 Constant shoulder score (0 to 100: best)

| Study or subgroup | Early (≤ 1 week) N | Mean(SD) | 3 weeks N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 6 weeks | | | | | | |
| Lefevre-Colau 2007 | 32 | 44 (16.5) | 32 | 33.9 (16.5) | | 10.10 [ 2.02, 18.18 ] |
| 2 3 months | | | | | | |
| Lefevre-Colau 2007 | 32 | 71 (14.6) | 32 | 61.1 (17) | | 9.90 [ 2.14, 17.66 ] |
| 3 6 months | | | | | | |
| Lefevre-Colau 2007 | 32 | 81.5 (11.2) | 32 | 75.4 (14.4) | | 6.10 [ -0.22, 12.42 ] |
| 4 6 months: subjective assessment (0 to 35: best) | | | | | | |
| Lefevre-Colau 2007 | 32 | 31.3 (4.4) | 32 | 29.4 (5.5) | | 1.90 [ -0.54, 4.34 ] |
| 5 6 months: objective assessment range of motion and strength (0 to 65: best) | | | | | | |
| Lefevre-Colau 2007 | 32 | 50.2 (8.9) | 32 | 46.1 (10.3) | | 4.10 [ -0.62, 8.82 ] |



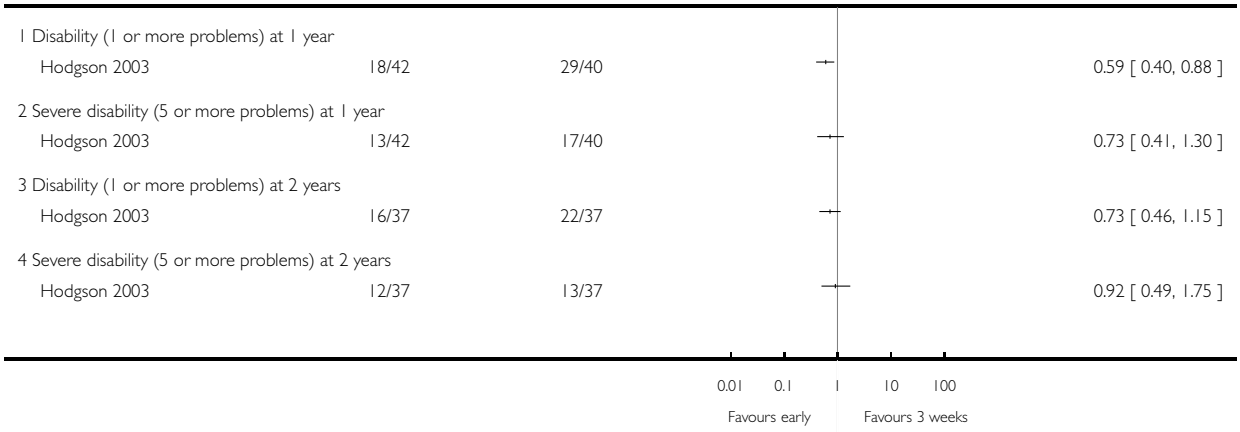
## Analysis 1.5. Comparison 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks, Outcome 5 Shoulder disability: Croft Shoulder Disability Score.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks

Outcome: 5 Shoulder disability: Croft Shoulder Disability Score

| Study or subgroup | Early (≤ 1 week) n/N | 3 weeks n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Disability (1 or more problems) at 1 year | | | | |
| Hodgson 2003 | 18/42 | 29/40 | | 0.59 [ 0.40, 0.88 ] |
| 2 Severe disability (5 or more problems) at 1 year | | | | |
| Hodgson 2003 | 13/42 | 17/40 | | 0.73 [ 0.41, 1.30 ] |
| 3 Disability (1 or more problems) at 2 years | | | | |
| Hodgson 2003 | 16/37 | 22/37 | | 0.73 [ 0.46, 1.15 ] |
| 4 Severe disability (5 or more problems) at 2 years | | | | |
| Hodgson 2003 | 12/37 | 13/37 | | 0.92 [ 0.49, 1.75 ] |

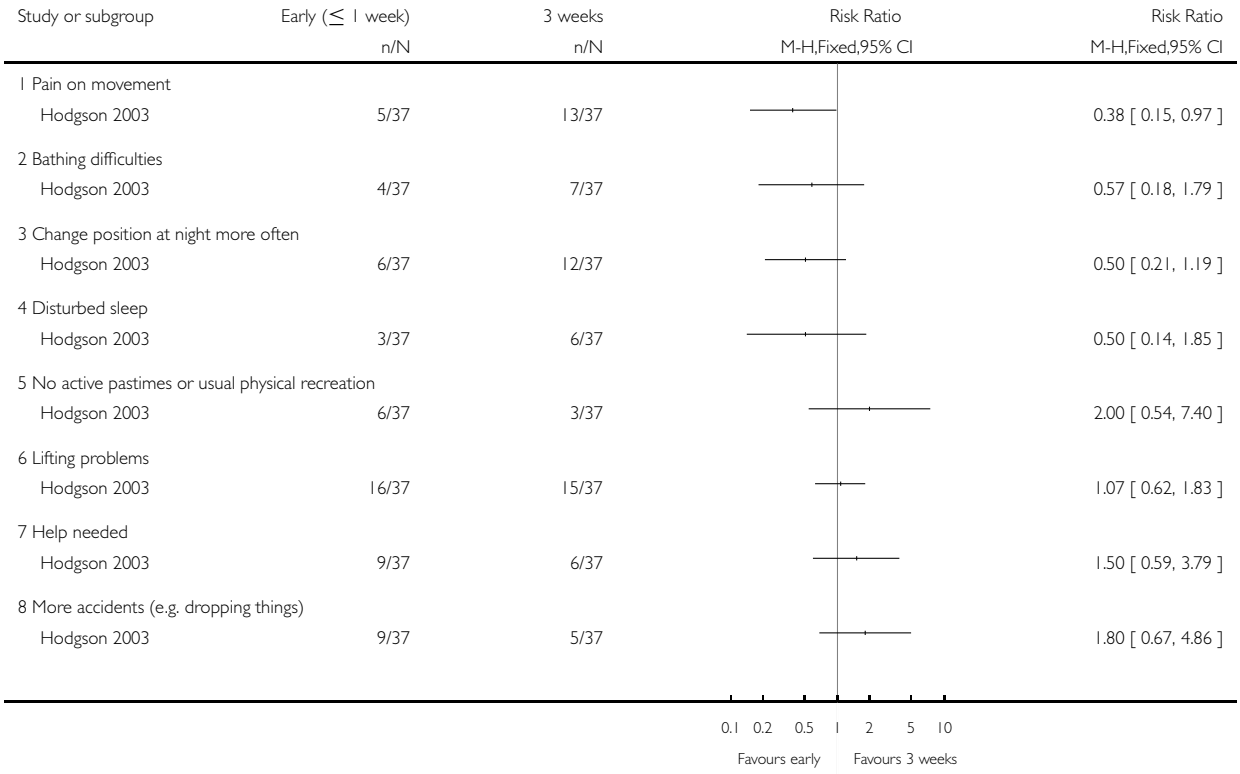


## Analysis 1.6. Comparison 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks, Outcome 6 Croft shoulder disability score: individual problems at 2 years.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks

Outcome: 6 Croft shoulder disability score: individual problems at 2 years



### Analysis 1.7. Comparison 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks, Outcome 7 Changes in pain intensity (mm) from baseline: 100 mm visual analogue scale (positive change = less pain).

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks

Outcome: 7 Changes in pain intensity (mm) from baseline: 100 mm visual analogue scale (positive change = less pain)

| Study or subgroup | Early (≤ 1 week) N | Mean(SD) | 3 weeks N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 At 6 weeks | | | | | | |
| Lefevre-Colau 2007 | 32 | 22.9 (34.1) | 32 | 19.3 (35.9) | | 3.60 [ -13.56, 20.76 ] |
| 2 At 3 months | | | | | | |
| Lefevre-Colau 2007 | 32 | 34.9 (25.8) | 32 | 19.2 (35.4) | | 15.70 [ 0.52, 30.88 ] |
| 3 At 6 months | | | | | | |
| Lefevre-Colau 2007 | 32 | 38.8 (25.5) | 32 | 39 (32) | | -0.20 [ -14.38, 13.98 ] |

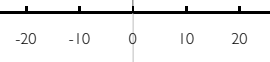

### Analysis 1.8. Comparison 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks, Outcome 8 Range of motion at 6 months (degrees): difference between two shoulders.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks

Outcome: 8 Range of motion at 6 months (degrees): difference between two shoulders

| Study or subgroup | Early (≤ 1 week) N | Mean(SD) | 3 weeks N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Abduction | | | | | | |
| Lefevre-Colau 2007 | 32 | 10.5 (12) | 32 | 17.1 (23.1) | | -6.60 [ -15.62, 2.42 ] |
| 2 Anterior elevation | | | | | | |
| Lefevre-Colau 2007 | 32 | 10.6 (11.3) | 32 | 14.2 (14.5) | | -3.60 [ -9.97, 2.77 ] |
| 3 Lateral rotation | | | | | | |
| Lefevre-Colau 2007 | 32 | 11.7 (10.6) | 32 | 14.2 (16.2) | | -2.50 [ -9.21, 4.21 ] |



### Analysis 1.9. Comparison 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks, Outcome 9 Complications.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks

Outcome: 9 Complications

| Study or subgroup | Early (≤ 1 week) n/N | 3 weeks n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Frozen shoulder | | | | |
| Hodgson 2003 | 0/40 | 1/40 | | 0.33 [ 0.01, 7.95 ] |
| 2 Fracture displacement | | | | |
| Lefevre-Colau 2007 | 0/32 | 0/32 | | 0.0 [ 0.0, 0.0 ] |
| 3 Non-union | | | | |
| Lefevre-Colau 2007 | 0/32 | 0/32 | | 0.0 [ 0.0, 0.0 ] |
| 4 Reflex sympathetic dystrophy | | | | |
| Kristiansen 1989 | 1/35 | 1/38 | | 1.09 [ 0.07, 16.71 ] |
| 5 Treated (injection) subacromial impingement | | | | |
| Lefevre-Colau 2007 | 1/32 | 1/32 | | 1.00 [ 0.07, 15.30 ] |


### Analysis 1.10. Comparison 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks, Outcome 10 Patient dissatisfied with treatment.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 1 Early mobilisation (within or up to 1 week) versus immobilisation for 3 weeks

Outcome: 10 Patient dissatisfied with treatment

| Study or subgroup | Early (≤ 1 week) n/N | 3 weeks n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Lefevre-Colau 2007 | 1/32 | 2/32 | | 0.50 [ 0.05, 5.24 ] |

### Analysis 2.1. Comparison 2 Gilchrist bandage versus 'Classic' Desault bandage, Outcome 1 Problems with bandages.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 2 Gilchrist bandage versus 'Classic' Desault bandage

Outcome: 1 Problems with bandages

| Study or subgroup | Gilchrist n/N | Desault n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Application of bandage was uncomfortable | | | | |
| Rommens 1993 | 4/14 | 7/14 | | 0.57 [ 0.21, 1.52 ] |
| 2 Premature bandage removal | | | | |
| Rommens 1993 | 0/14 | 2/12 | | 0.17 [ 0.01, 3.29 ] |


### Analysis 2.2. Comparison 2 Gilchrist bandage versus 'Classic' Desault bandage, Outcome 2 Fracture displacement by 3 weeks.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 2 Gilchrist bandage versus 'Classic' Desault bandage

Outcome: 2 Fracture displacement by 3 weeks

| Study or subgroup | Gilchrist n/N | Desault n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Rommens 1993 | 2/14 | 0/12 | | 4.33 [ 0.23, 82.31 ] |

### Analysis 2.3. Comparison 2 Gilchrist bandage versus 'Classic' Desault bandage, Outcome 3 Poor or bad rating by patient at fracture consolidation.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 2 Gilchrist bandage versus 'Classic' Desault bandage

Outcome: 3 Poor or bad rating by patient at fracture consolidation

| Study or subgroup | Gilchrist n/N | Desault n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Rommens 1993 | 2/14 | 8/14 | | 0.25 [ 0.06, 0.97 ] |


### Analysis 3.1. Comparison 3 Instructed self physiotherapy versus conventional physiotherapy, Outcome 1 Pain at one year (scale 0 to 8: maximum pain).

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 3 Instructed self physiotherapy versus conventional physiotherapy

Outcome: 1 Pain at one year (scale 0 to 8: maximum pain)

| Study or subgroup | Instructions N | Mean(SD) | Physiotherapy N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| Bertoft 1984 | 7 | 0.6 (1) | 6 | 1 (1.7) | | -0.40 [ -1.95, 1.15 ] |

### Analysis 3.2. Comparison 3 Instructed self physiotherapy versus conventional physiotherapy, Outcome 2 Severe or moderate pain at 3 months.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 3 Instructed self physiotherapy versus conventional physiotherapy

Outcome: 2 Severe or moderate pain at 3 months

| Study or subgroup | Instructions n/N | Physiotherapy n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Lundberg 1979 | 4/20 | 2/22 | | 2.20 [ 0.45, 10.74 ] |


### Analysis 3.3. Comparison 3 Instructed self physiotherapy versus conventional physiotherapy, Outcome 3 Requested change of therapy.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 3 Instructed self physiotherapy versus conventional physiotherapy

Outcome: 3 Requested change of therapy

| Study or subgroup | Instructions n/N | Physiotherapy n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Bertoft 1984 | 1/10 | 2/8 | | 0.40 [ 0.04, 3.66 ] |

### Analysis 3.4. Comparison 3 Instructed self physiotherapy versus conventional physiotherapy, Outcome 4 Complications (frozen shoulder: 1 v 2; unexplained prolonged pain: 0 v 1).

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 3 Instructed self physiotherapy versus conventional physiotherapy

Outcome: 4 Complications (frozen shoulder: 1 v 2; unexplained prolonged pain: 0 v 1)

| Study or subgroup | Instructions n/N | Physiotherapy n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Lundberg 1979 | 1/20 | 3/22 | | 0.37 [ 0.04, 3.25 ] |


### Analysis 3.5. Comparison 3 Instructed self physiotherapy versus conventional physiotherapy, Outcome 5 Neer's rating (0 to 100: best) at mean 16 months (exploratory analysis).

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 3 Instructed self physiotherapy versus conventional physiotherapy

Outcome: 5 Neer's rating (0 to 100: best) at mean 16 months (exploratory analysis)

| Study or subgroup | Instructions N | Mean(SD) | Physiotherapy N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| Lundberg 1979 | 20 | 83.5 (22.36) | 22 | 86.6 (19.7) | | -3.10 [ -15.90, 9.70 ] |

### Analysis 3.6. Comparison 3 Instructed self physiotherapy versus conventional physiotherapy, Outcome 6 Active gleno-humeral elevation (degrees).

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 3 Instructed self physiotherapy versus conventional physiotherapy

Outcome: 6 Active gleno-humeral elevation (degrees)

| Study or subgroup | Instructions N | Mean(SD) | Physiotherapy N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| Lundberg 1979 | 20 | 59.3 (17) | 22 | 59.52 (20.64) | | -0.22 [ -11.62, 11.18 ] |


### Analysis 4.1. Comparison 4 Reduction and external fixation versus closed reduction, Outcome 1 Treatment failure by 1 month.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 4 Reduction and external fixation versus closed reduction

Outcome: 1 Treatment failure by 1 month

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Treatment failure | | | | |
| Kristiansen 1988 | 1/15 | 2/16 | | 0.53 [ 0.05, 5.29 ] |
| 2 Poor immediate reduction | | | | |
| Kristiansen 1988 | 0/15 | 2/16 | | 0.21 [ 0.01, 4.10 ] |
| 3 Infection resulting in removal of pins | | | | |
| Kristiansen 1988 | 1/15 | 0/16 | | 3.19 [ 0.14, 72.69 ] |

### Analysis 4.2. Comparison 4 Reduction and external fixation versus closed reduction, Outcome 2 Poor or unsatisfactory function at 1 year (Neer rating).

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 4 Reduction and external fixation versus closed reduction

Outcome: 2 Poor or unsatisfactory function at 1 year (Neer rating)

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Kristiansen 1988 | 3/11 | 6/10 | | 0.45 [ 0.15, 1.35 ] |


### Analysis 4.3. Comparison 4 Reduction and external fixation versus closed reduction, Outcome 3 Complications.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 4 Reduction and external fixation versus closed reduction

Outcome: 3 Complications

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Avascular necrosis at 1 year | | | | |
| Kristiansen 1988 | 1/11 | 2/10 | | 0.45 [ 0.05, 4.28 ] |
| 2 Non-union | | | | |
| Kristiansen 1988 | 1/11 | 4/11 | | 0.25 [ 0.03, 1.90 ] |
| 3 Refracture | | | | |
| Kristiansen 1988 | 1/11 | 1/11 | | 1.00 [ 0.07, 14.05 ] |

## Analysis 5.1. Comparison 5 Cerclage or tension band wiring versus conservative treatment (displaced 3 and 4 part fractures), Outcome 1 Complications.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 5 Cerclage or tension band wiring versus conservative treatment (displaced 3 and 4 part fractures)

Outcome: 1 Complications

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Infection at 1 year | | | | |
| Zyto 1997 | 2/19 | 0/19 | | 5.00 [ 0.26, 97.70 ] |
| 2 Avascular necrosis at 1 year | | | | |
| Zyto 1997 | 1/19 | 0/19 | | 3.00 [ 0.13, 69.31 ] |
| 3 Non union at 1 year | | | | |
| Zyto 1997 | 1/19 | 0/19 | | 3.00 [ 0.13, 69.31 ] |
| 4 Wire penetration at 1 year | | | | |
| Zyto 1997 | 1/19 | 0/19 | | 3.00 [ 0.13, 69.31 ] |
| 5 Osteoarthritis at 50 months | | | | |
| Zyto 1997 | 2/14 | 2/15 | | 1.07 [ 0.17, 6.61 ] |
| 6 Tuberosity displacement at 50 months | | | | |
| Zyto 1997 | 0/14 | 3/15 | | 0.15 [ 0.01, 2.71 ] |

## Analysis 5.2. Comparison 5 Cerclage or tension band wiring versus conservative treatment (displaced 3 and 4 part fractures), Outcome 2 Activities of dailiy living.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 5 Cerclage or tension band wiring versus conservative treatment (displaced 3 and 4 part fractures)

Outcome: 2 Activities of dailiy living

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Unable to manage personal hygiene at 1 year | | | | |
| Zyto 1997 | 6/19 | 5/19 | | 1.20 [ 0.44, 3.27 ] |
| 2 Unable to comb hair at 1 year | | | | |
| Zyto 1997 | 3/19 | 3/19 | | 1.00 [ 0.23, 4.34 ] |
| 3 Unable to sleep on fractured side at 1 year | | | | |
| Zyto 1997 | 6/19 | 4/19 | | 1.50 [ 0.50, 4.48 ] |
| 4 Unable to carry 5 kg at 1 year | | | | |
| Zyto 1997 | 10/19 | 8/19 | | 1.25 [ 0.63, 2.46 ] |
| 5 Unable to manage personal hygiene at 50 months | | | | |
| Zyto 1997 | 1/14 | 4/15 | | 0.27 [ 0.03, 2.12 ] |
| 6 Unable to comb hair at 50 months | | | | |
| Zyto 1997 | 2/14 | 3/15 | | 0.71 [ 0.14, 3.66 ] |
| 7 Unable to sleep on fractured side at 50 months | | | | |
| Zyto 1997 | 3/14 | 2/15 | | 1.61 [ 0.31, 8.24 ] |
| 8 Unable to carry 5 kg at 50 months | | | | |
| Zyto 1997 | 5/14 | 7/15 | | 0.77 [ 0.32, 1.86 ] |

## Analysis 5.3. Comparison 5 Cerclage or tension band wiring versus conservative treatment (displaced 3 and 4 part fractures), Outcome 3 Constant score at 50 months: overall and components.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 5 Cerclage or tension band wiring versus conservative treatment (displaced 3 and 4 part fractures)

Outcome: 3 Constant score at 50 months: overall and components

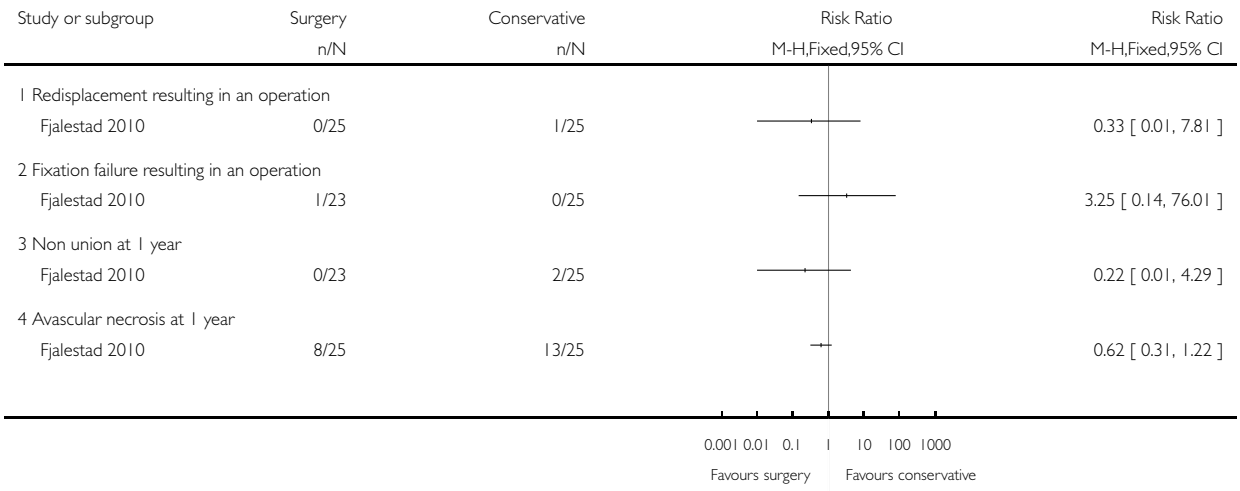
| Study or subgroup | Surgery N | Mean(SD) | Conservative N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Overall score (0-100: best score) | | | | | | |
| Zyto 1997 | 14 | 60 (19) | 15 | 65 (15) | | -5.00 [ -17.52, 7.52 ] |
| 2 Pain (maximum score 15) | | | | | | |
| Zyto 1997 | 14 | 10 (5) | 15 | 12 (3) | | -2.00 [ -5.03, 1.03 ] |
| 3 Range of motion (maximum score 40) | | | | | | |
| Zyto 1997 | 14 | 26 (4) | 15 | 29 (3) | | -3.00 [ -5.59, -0.41 ] |
| 4 Power (maximum score 25) | | | | | | |
| Zyto 1997 | 14 | 8 (5) | 15 | 8 (5) | | 0.0 [ -3.64, 3.64 ] |
| 5 Activities of daily living (maximum score 20) | | | | | | |
| Zyto 1997 | 14 | 16 (5) | 15 | 16 (4) | | 0.0 [ -3.31, 3.31 ] |

### Analysis 6.1. Comparison 6 Plating plus cerclage versus conservative treatment (displaced 3 and 4 part fractures), Outcome 1 Complications.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 6 Plating plus cerclage versus conservative treatment (displaced 3 and 4 part fractures)

Outcome: 1 Complications

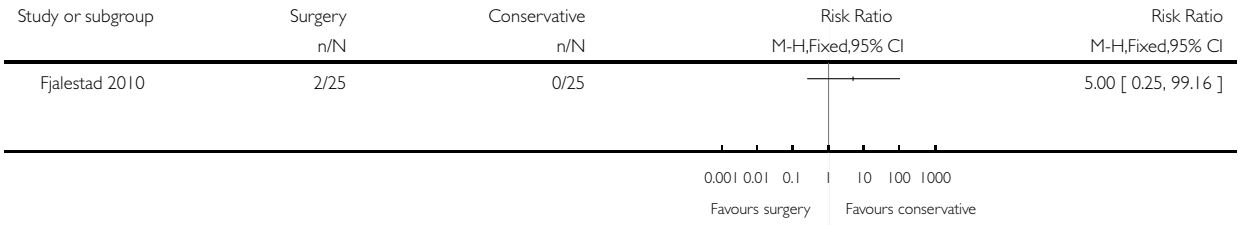



### Analysis 6.2. Comparison 6 Plating plus cerclage versus conservative treatment (displaced 3 and 4 part fractures), Outcome 2 Mortality at 1 year.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 6 Plating plus cerclage versus conservative treatment (displaced 3 and 4 part fractures)

Outcome: 2 Mortality at 1 year



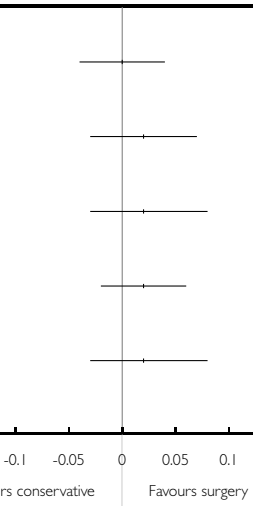
### Analysis 6.3. Comparison 6 Plating plus cerclage versus conservative treatment (displaced 3 and 4 part fractures), Outcome 3 Quality of life assessment.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 6 Plating plus cerclage versus conservative treatment (displaced 3 and 4 part fractures)

Outcome: 3 Quality of life assessment

| Study or subgroup | Surgery N | Mean(SD) | Conservative N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 15D at 3 months (0: death; 1: perfect health) | | | | | | |
| Fjalestad 2010 | 23 | 0.814 (0.062) | 25 | 0.82 (0.074) | | 0.00 [ -0.04, 0.04 ] |
| 2 15D at 6 months | | | | | | |
| Fjalestad 2010 | 23 | 0.836 (0.083) | 25 | 0.82 (0.088) | | 0.02 [ -0.03, 0.07 ] |
| 3 15D at 12 months | | | | | | |
| Fjalestad 2010 | 23 | 0.841 (0.105) | 25 | 0.82 (0.083) | | 0.02 [ -0.03, 0.08 ] |
| 4 number of QALYs at 1 year | | | | | | |
| Fjalestad 2010 | 25 | 0.837 (0.076) | 25 | 0.82 (0.082) | | 0.02 [ -0.02, 0.06 ] |
| 5 numbers of QALYs at 1 year (- deaths) | | | | | | |
| Fjalestad 2010 | 23 | 0.841 (0.105) | 25 | 0.82 (0.083) | | 0.02 [ -0.03, 0.08 ] |




### Analysis 6.4. Comparison 6 Plating plus cerclage versus conservative treatment (displaced 3 and 4 part fractures), Outcome 4 Costs at 1 year (Euros in 2005).

**Costs at 1 year (Euros in 2005)**

| Study | Measure | Surgery | Conservative treatment | Difference (conclusion) |
|---|---|---|---|---|
| Fjalestad 2010 | Total health-care costs | mean = 10,367 | mean = 10,946 | Abstract: "the mean difference in total health-care costs was 597 Euros in favour of surgery (95% CI = -5291, 3777)". No significant difference. |
| Fjalestad 2010 | Health-care + indirect costs | mean = 23,953 | mean = 21,878 | Reformatted text: "Including indirect costs... the difference [was] 2,075 (95% CI = -15,949 to 20,100)". No significant difference, but favours the conservative group. |

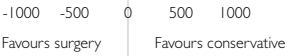
### Analysis 6.5. Comparison 6 Plating plus cerclage versus conservative treatment (displaced 3 and 4 part fractures), Outcome 5 Total costs including indirect costs (Euros) at 1 year.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 6 Plating plus cerclage versus conservative treatment (displaced 3 and 4 part fractures)

Outcome: 5 Total costs including indirect costs (Euros) at 1 year

| Study or subgroup | Surgery N | Mean(SD) | Conservative N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| Fjalestad 2010 | 25 | 23953 (34596) | 25 | 21878 (22696) | 2075.00 [ -14144.18, 18294.18 ] | |




### Analysis 7.1. Comparison 7 Hemi-arthroplasty versus closed reduction (4 part fractures), Outcome 1 Deep infection.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 7 Hemi-arthroplasty versus closed reduction (4 part fractures)

Outcome: 1 Deep infection

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Stableforth 1984 | 1/16 | 0/16 | | 3.00 [ 0.13, 68.57 ] |

### Analysis 7.2. Comparison 7 Hemi-arthroplasty versus closed reduction (4 part fractures), Outcome 2 Dead at 6 months.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 7 Hemi-arthroplasty versus closed reduction (4 part fractures)

Outcome: 2 Dead at 6 months

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Stableforth 1984 | 1/16 | 1/16 | | 1.00 [ 0.07, 14.64 ] |


### Analysis 7.3. Comparison 7 Hemi-arthroplasty versus closed reduction (4 part fractures), Outcome 3 Dependent in activities of daily living (or dead) at 6 months.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 7 Hemi-arthroplasty versus closed reduction (4 part fractures)

Outcome: 3 Dependent in activities of daily living (or dead) at 6 months

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Stableforth 1984 | 2/16 | 9/16 | | 0.22 [ 0.06, 0.87 ] |

### Analysis 7.4. Comparison 7 Hemi-arthroplasty versus closed reduction (4 part fractures), Outcome 4 Constant (often severe) pain at 6 months.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 7 Hemi-arthroplasty versus closed reduction (4 part fractures)

Outcome: 4 Constant (often severe) pain at 6 months

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Stableforth 1984 | 2/15 | 9/15 | | 0.22 [ 0.06, 0.86 ] |


### Analysis 7.5. Comparison 7 Hemi-arthroplasty versus closed reduction (4 part fractures), Outcome 5 Failure to recover 75% muscle power relative to other arm (survivors) at 6 months.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 7 Hemi-arthroplasty versus closed reduction (4 part fractures)

Outcome: 5 Failure to recover 75% muscle power relative to other arm (survivors) at 6 months

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Flexion | | | | |
| Stableforth 1984 | 3/15 | 7/15 | | 0.43 [ 0.14, 1.35 ] |
| 2 Abduction | | | | |
| Stableforth 1984 | 5/15 | 9/15 | | 0.56 [ 0.24, 1.27 ] |
| 3 Lateral rotation | | | | |
| Stableforth 1984 | 1/15 | 7/15 | | 0.14 [ 0.02, 1.02 ] |

### Analysis 7.6. Comparison 7 Hemi-arthroplasty versus closed reduction (4 part fractures), Outcome 6 Range of movement impairments in survivors at 6 months.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 7 Hemi-arthroplasty versus closed reduction (4 part fractures)

Outcome: 6 Range of movement impairments in survivors at 6 months

| Study or subgroup | Surgery n/N | Conservative n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Flexion < 45 degrees | | | | |
| Stableforth 1984 | 1/15 | 7/15 | | 0.14 [ 0.02, 1.02 ] |
| 2 Unable to place thumb on mid spine (T12) | | | | |
| Stableforth 1984 | 0/15 | 7/15 | | 0.07 [ 0.00, 1.07 ] |
| 3 Lateral rotation < 5 degrees | | | | |
| Stableforth 1984 | 2/15 | 10/15 | | 0.20 [ 0.05, 0.76 ] |


### Analysis 8.1. Comparison 8 Hemi-arthroplasty versus tension band wiring (4 part fractures), Outcome 1 Re-operation at 1 year.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 8 Hemi-arthroplasty versus tension band wiring (4 part fractures)

Outcome: 1 Re-operation at 1 year

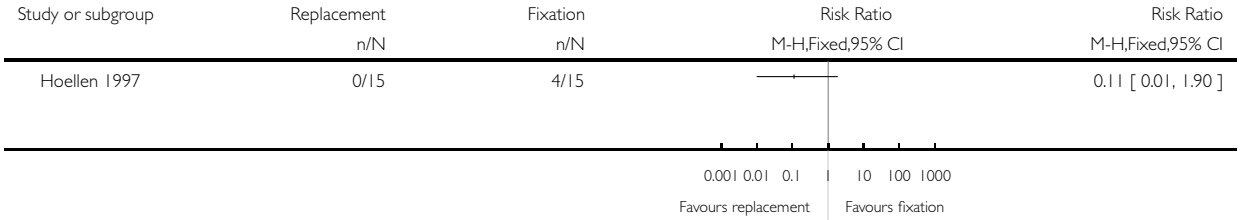
| Study or subgroup | Replacement n/N | Fixation n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Hoellen 1997 | 0/15 | 5/15 | | 0.09 [ 0.01, 1.51 ] |

### Analysis 8.2. Comparison 8 Hemi-arthroplasty versus tension band wiring (4 part fractures), Outcome 2 Implant removal at 1 year.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 8 Hemi-arthroplasty versus tension band wiring (4 part fractures)

Outcome: 2 Implant removal at 1 year

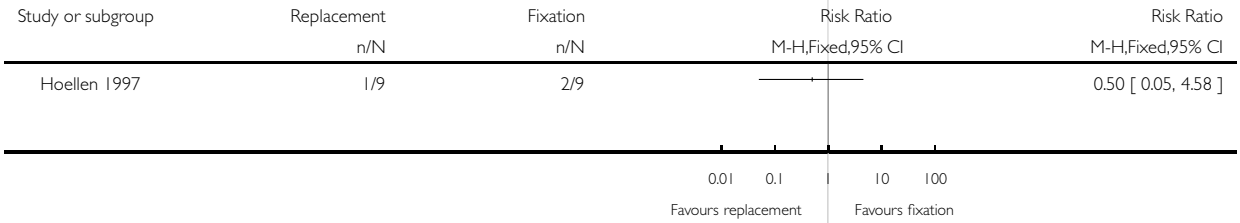



### Analysis 8.3. Comparison 8 Hemi-arthroplasty versus tension band wiring (4 part fractures), Outcome 3 Pain at 1 year.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 8 Hemi-arthroplasty versus tension band wiring (4 part fractures)

Outcome: 3 Pain at 1 year




### Analysis 9.1. Comparison 9 Hemiarthoplasty: EPOCA prosthesis versus HAS prosthesis, Outcome 1 Range of motion results at one year (degrees).

**Range of motion results at one year (degrees)**

| Study | Measure | Early ambulation | Delayed ambulation | Reported significance |
|---|---|---|---|---|
| Fialka 2008 | Active forward flexion | mean = 109°<br>range = 30° to 150° | mean = 62°<br>range = 20° to 110° | P < 0.001 |
| Fialka 2008 | Active abduction | mean = 101°<br>range = 30° to 150° | mean = 62°<br>range = 30° to 100° | P = 0.001 |

**Range of motion results at one year (degrees)** (*Continued*)

| | | | | |
|---|---|---|---|---|
| Fialka 2008 | Active external rotation in 90° abduction | mean = 30°<br>range = 0° to 60° | mean = 17°<br>range = 0° to 40° | P = 0.01 |
| Fialka 2008 | Active external rotation in 90° abduction | mean = 45°<br>range = 0° to 70° | mean = 13°<br>range = 0° to 40° | P = 0.001 |

### Analysis 9.2. Comparison 9 Hemiarthoplasty: EPOCA prosthesis versus HAS prosthesis, Outcome 2 Complications.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 9 Hemiarthoplasty: EPOCA prosthesis versus HAS prosthesis

Outcome: 2 Complications

| Study or subgroup | EPOCA prosthesis n/N | HAS prosthesis n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Deep infection | | | | |
| Fialka 2008 | 2/18 | 0/17 | | 4.74 [ 0.24, 92.07 ] |
| 2 Persistent pain - scheduled for reoperation | | | | |
| Fialka 2008 | 0/18 | 2/17 | | 0.19 [ 0.01, 3.68 ] |

### Analysis 9.3. Comparison 9 Hemiarthoplasty: EPOCA prosthesis versus HAS prosthesis, Outcome 3 Radiological assessment.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 9 Hemiarthoplasty: EPOCA prosthesis versus HAS prosthesis

Outcome: 3 Radiological assessment

| Study or subgroup | EPOCA prosthesis n/N | HAS prosthesis n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Resorption of tuberosities | | | | |
| Fialka 2008 | 2/18 | 8/17 | | 0.24 [ 0.06, 0.96 ] |
| 2 Secondary dislocation of tuberosities | | | | |
| Fialka 2008 | 0/18 | 0/17 | | 0.0 [ 0.0, 0.0 ] |
| 3 Superior migration of prosthesis | | | | |
| Fialka 2008 | 2/18 | 11/17 | | 0.17 [ 0.04, 0.66 ] |
| 4 Anterior subluxations | | | | |
| Fialka 2008 | 3/18 | 1/17 | | 2.83 [ 0.33, 24.66 ] |
| 5 Glenoid erosion | | | | |
| Fialka 2008 | 1/18 | 6/17 | | 0.16 [ 0.02, 1.18 ] |
| 6 Aseptic loosening of stem | | | | |
| Fialka 2008 | 0/18 | 0/17 | | 0.0 [ 0.0, 0.0 ] |

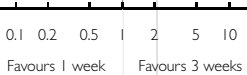

### Analysis 10.1. Comparison 10 Post-operative (percutaneous fixation) immobilisation for 1 week versus 3 weeks, Outcome 1 Neer score $\leq$ 80 points (unsatisfactory or failure) at 6 months.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 10 Post-operative (percutaneous fixation) immobilisation for 1 week versus 3 weeks

Outcome: 1 Neer score $\leq$ 80 points (unsatisfactory or failure) at 6 months

| Study or subgroup | 1 week n/N | 3 weeks n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| Wirbel 1999 | 9/32 | 10/32 | | 0.90 [ 0.42, 1.92 ] |



### Analysis 10.2. Comparison 10 Post-operative (percutaneous fixation) immobilisation for 1 week versus 3 weeks, Outcome 2 Premature removal of Kirschner wires.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 10 Post-operative (percutaneous fixation) immobilisation for 1 week versus 3 weeks

Outcome: 2 Premature removal of Kirschner wires

| Study or subgroup | 1 week | 3 weeks | Risk Ratio | Risk Ratio |
|---|---|---|---|---|
| | n/N | n/N | M-H,Fixed,95% CI | M-H,Fixed,95% CI |
| Wirbel 1999 | 5/32 | 5/32 | | 1.00 [ 0.32, 3.12 ] |


### Analysis 11.1. Comparison 11 Post-operative (hemiarthroplasty) mobilisation: early (2 weeks immobilisation) versus late (6 weeks), Outcome 1 Oxford Shoulder Score at 1 year (adjusted: 0 to 100 best).

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 11 Post-operative (hemiarthroplasty) mobilisation: early (2 weeks immobilisation) versus late (6 weeks)

Outcome: 1 Oxford Shoulder Score at 1 year (adjusted: 0 to 100 best)

| Study or subgroup | Early (after 2 weeks) | | Late (after 6 weeks) | | Mean Difference | Mean Difference |
|---|---|---|---|---|---|---|
| | N | Mean(SD) | N | Mean(SD) | IV,Fixed,95% CI | IV,Fixed,95% CI |
| Agorastides 2007 | 26 | 65 (23) | 23 | 71 (14) | | -6.00 [ -16.53, 4.53 ] |

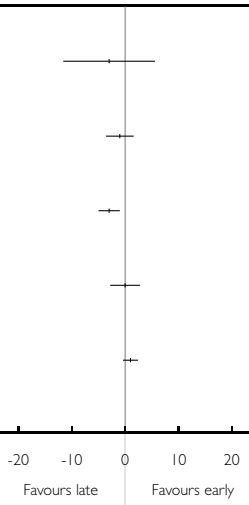
## Analysis 11.2. Comparison 11 Post-operative (hemiarthroplasty) mobilisation: early (2 weeks immobilisation) versus late (6 weeks), Outcome 2 Constant shoulder score (at 1 year).

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 11 Post-operative (hemiarthroplasty) mobilisation: early (2 weeks immobilisation) versus late (6 weeks)

Outcome: 2 Constant shoulder score (at 1 year)

| Study or subgroup | Early (after 2 weeks) N | Mean(SD) | Late (after 6 weeks) N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Overall score (0 to 100: best) | | | | | | |
| Agorastides 2007 | 26 | 47 (19) | 23 | 50 (11) | | -3.00 [ -11.58, 5.58 ] |
| 2 Pain component (0 to 15: best)) | | | | | | |
| Agorastides 2007 | 26 | 10 (5) | 23 | 11 (4) | | -1.00 [ -3.52, 1.52 ] |
| 3 Activities of daily living component (0 to 25: best) | | | | | | |
| Agorastides 2007 | 26 | 13 (4) | 23 | 16 (3) | | -3.00 [ -4.97, -1.03 ] |
| 4 Mobility component (0 to 40: best) | | | | | | |
| Agorastides 2007 | 26 | 18 (5) | 23 | 18 (5) | | 0.0 [ -2.81, 2.81 ] |
| 5 Strength component (0 to 25: best) | | | | | | |
| Agorastides 2007 | 26 | 6 (3) | 23 | 5 (2) | | 1.00 [ -0.41, 2.41 ] |



### Analysis 11.3. Comparison 11 Post-operative (hemiarthroplasty) mobilisation: early (2 weeks immobilisation) versus late (6 weeks), Outcome 3 Radiological assessment.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 11 Post-operative (hemiarthroplasty) mobilisation: early (2 weeks immobilisation) versus late (6 weeks)

Outcome: 3 Radiological assessment

| Study or subgroup | Early (after 2 weeks) n/N | Late (after 6 weeks) n/N | Risk Ratio M-H,Fixed,95% CI | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|
| 1 Nonunion (with bone resorption) | | | | |
| Agorastides 2007 | 2/26 | 0/23 | | 4.44 [ 0.22, 88.04 ] |
| 2 Malunion | | | | |
| Agorastides 2007 | 1/26 | 1/23 | | 0.88 [ 0.06, 13.35 ] |
| 3 Greater tuberosity migration (all had severe pain at 6 % 12 months) | | | | |
| Agorastides 2007 | 3/26 | 1/23 | | 2.65 [ 0.30, 23.77 ] |
| 4 Superior luxation of prosthesis | | | | |
| Agorastides 2007 | 6/26 | 4/23 | | 1.33 [ 0.43, 4.12 ] |

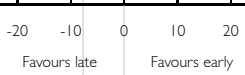

### Analysis 11.4. Comparison 11 Post-operative (hemiarthroplasty) mobilisation: early (2 weeks immobilisation) versus late (6 weeks), Outcome 4 Range of motion at 1 year.

Review: Interventions for treating proximal humeral fractures in adults

Comparison: 11 Post-operative (hemiarthroplasty) mobilisation: early (2 weeks immobilisation) versus late (6 weeks)

Outcome: 4 Range of motion at 1 year

| Study or subgroup | Early (after 2 weeks) N | Mean(SD) | Late (after 6 weeks) N | Mean(SD) | Mean Difference IV,Fixed,95% CI | Mean Difference IV,Fixed,95% CI |
|---|---|---|---|---|---|---|
| 1 Elevation (degrees) | | | | | | |
| Agorastides 2007 | 26 | 80 (17) | 23 | 78 (13) | | 2.00 [ -6.42, 10.42 ] |
| 2 External rotation (degrees) | | | | | | |
| Agorastides 2007 | 26 | 14 (7) | 23 | 18 (10) | | -4.00 [ -8.89, 0.89 ] |



# APPENDICES

## Appendix 1. Search strategies

### The Cochrane Library (Wiley Interscience)

1. MeSH descriptor Shoulder Fractures explode all trees
2. MeSH descriptor Humeral Fractures explode all trees
3. MeSH descriptor Humerus explode all trees
4. (shoulder* OR humer*)
5. fract*
6. (#3 or #4)
7. (#1 or #2)
8 (#5 and #6)
9. (#7 or #8)

### MEDLINE (OVID WEB)

1. Shoulder Fractures/
2. Humeral Fractures/
3. ((humer$ or shoulder$) adj10 (fracture$ or fixat$)).tw.
4. or/2-3
5. (proximal or neck$1 or sub?capital).tw.
6. and/4-5
7. or/1,6
8. randomized controlled trial.pt.
9. controlled clinical trial.pt.
10. Randomized Controlled Trials/
11. Random Allocation/
12. Double Blind Method/
13. Single Blind Method/
14. or/8-13
15. Animals/ not Humans/
16. 14 not 15
17. clinical trial.pt.
18. exp Clinical Trials as topic/
19. (clinic$ adj25 trial$).tw.
20. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
21. Placebos/
22. placebo$.tw.
23. random$.tw.
24. Research Design/
25. or/17-24
26. 25 not 15
27. 26 not 16
28. or/16,27
29. and/7,28

### EMBASE (OVID WEB)

1. Humerus Fracture/
2. ((humer$ or shoulder$) adj10 (fract$ or fixat$)).tw.

3. or/1-2
4. (proximal or neck$1 or sub?capital).tw.
5. and/3-4
6. exp Randomized Controlled Trial/
7. exp Double Blind Procedure/
8. exp Single Blind Procedure/
9. exp Crossover Procedure/
10. Controlled Study/
11. or/6-10
12. ((clinical or controlled or comparative or placebo or prospective$ or randomi#ed) adj3 (trial or study)).tw.
13. (random$ adj7 (allocat$ or allot$ or assign$ or basis$ or divid$ or order$)).tw.
14. ((singl$ or doubl$ or trebl$ or tripl$) adj7 (blind$ or mask$)).tw.
15. (cross?over$ or (cross adj1 over$)).tw.
16. ((allocat$ or allot$ or assign$ or divid$) adj3 (condition$ or experiment$ or intervention$ or treatment$ or therap$ or control$ or group$)).tw.
17. or/12-16
18. or/11,17
19. Limit 18 to human
20. and/5,19

### CINAHL (EBSCO)

S1 (MH "Shoulder Fractures")
S2 (MH "Humeral Fractures")
S3 (MH "Humerus/IN/SU")
S4 TX ( humer* or shoulder* ) and TX ( fracture* or fixat* )
S5 S2 or S3 or S4
S6 TX proximal or neck or subcapital or sub-capital
S7 S5 and S6
S8 S1 or S7
S9 (MH "Clinical Trials+")
S10 (MH "Evaluation Research+")
S11 (MH "Comparative Studies")
S12 (MH "Crossover Design")
S13 PT Clinical trial
S14 S9 or S10 or S11 or S12 or S13
S15 TX ( clinical or controlled or comparative or placebo or prospective or randomised or randomized ) and TX ( trial or study )
S16 TX random* and TX ( allocat* or allot* or assign* or basis* or divid* or order* )
S17 TX ( singl* or doubl* or trebl* or tripl* ) and TX ( blind* or mask* )
S18 TX crossover* or cross-over or "cross over"
S19 TX ( allocat* or allot* or assign* or divid* ) and TX ( condition* or experiment* or intervention* or treatment* or therap* or control* or group* )
S20 S15 or S16 or S17 or S18 or S19
S21 S14 or S20
S22 S8 and S21

## Appendix 2. Previous methodological quality assessment tool (used before 2010)

| Items | Scores | Notes |
|---|---|---|
| 1. Was the assigned treatment adequately concealed prior to allocation? | 3 = method did not allow disclosure of assignment.<br>1 = small but possible chance of disclosure of assignment or unclear.<br>0 = quasi-randomised or open list/tables. | Cochrane code (see Handbook): Clearly Yes = A; Not sure = B; Clearly no = C. |
| 2. Were the outcomes of trial participants who withdrew described and included in the analyses, and all participants analysed according to the group allocated at randomisation (intention to treat)? | 3 = withdrawals well described and accounted for in analysis.<br>1 = withdrawals described and analysis not possible.<br>0 = no mention, inadequate mention, or obvious differences and no adjustment. | |
| 3. Were the outcome assessors blinded to treatment status? | 3 = effective action taken to blind assessors.<br>1 = small or moderate chance of unblinding of assessors, or some blinding of outcomes attempted.<br>0 = not mentioned or not possible. | |
| 4. Were important baseline characteristics reported and comparable? | 3 = good comparability of groups, or confounding adjusted for in analysis.<br>1 = confounding small, mentioned but not adjusted for, or comparability reported in text without confirmatory data.<br>0 = large potential for confounding, or not discussed. | The principal confounders were considered to be age, gender and type of fracture. |
| 5. Were the trial participants blind to assignment status after allocation? | 3 = effective action taken to blind participants.<br>1 = small or moderate chance of unblinding of participants.<br>0 = not possible, not mentioned, or possible but not done. | |
| 6. Were the treatment providers blind to assignment status? | 3 = effective action taken to blind treatment providers.<br>1 = small or moderate chance of unblinding of treatment providers.<br>0 = not possible, not mentioned, or possible but not done. | |
| 7. Were care programmes, other than the trial options, identical? | 3 = care programmes clearly identical.<br>1 = clear but trivial differences, or some evidence of comparability.<br>0 = not mentioned or clear and important differences in care programmes. | Examples of clinically important differences in other interventions were considered to be time of intervention, duration of intervention, anaesthetic used within broad categories and differences in rehabilitation. |

(*Continued*)

| | | |
|---|---|---|
| 8. Were the inclusion and exclusion criteria for entry clearly defined? | 3 = clearly defined (including fracture type and appropriate exclusion criteria; e.g. impaired ability to comprehend instructions for exercises in trials evaluating self-exercises).<br>1 = inadequately defined.<br>0 = not defined. | |
| 9. Were the outcome measures used clearly defined? | 3 = clearly defined.<br>1 = inadequately defined.<br>0 = not defined. | |
| 10. Were the outcome measures comprehensive, clinically useful and valid? | 3 = Yes. Assessment of outcome comprehensive, clinically useful with some measures taken to validate outcome assessment.<br>1 = Adequate outcome assessment and clinically useful but inadequate descriptions of outcome measurement and no validity measures.<br>0 = No: incomplete assessment, no description of outcome measures. | |
| 11. Was the surveillance active, and of clinically appropriate duration? | 3 = active surveillance and appropriate duration (1 year and above).<br>1 = active surveillance and adequate duration (6 months up to 1 year).<br>0 = not active surveillance, or not defined or inadequate duration (under 6 months). | |

**Notes:** In versions of the review before issue 3, 2010, a development of the former Cochrane Bone, Joint and Muscle Trauma Group quality assessment tool was used in the evaluation of all the included trials. At minimum, two review authors independently assessed each paper, without masking of journal sources, authors and supporting institutions. The above table shows the scoring scheme based on 11 aspects of trial methodology. From the fourth update (Issue 2, 2007) of the review, the scores of the individual items for each trial were no longer summed.

## Appendix 3. Numbers and status of studies in the published versions of the review

| Version | Trial status | Changes |
|---|---|---|
| Ist version<br>Issue 1, 2001 | The original review had 9 included studies, 4 excluded studies and 6 studies listed as ongoing. | |

(*Continued*)

| | | |
|---|---|---|
| 2nd version (substantive update)<br>Issue 2, 2002 | This update had 10 included studies, 9 excluded studies, 3 studies listed as ongoing and 1 study awaiting assessment. | Of the four newly identified studies, one (Stableforth 1984) was included, one (Warnecke 1999) was excluded, one (Dias 2001) listed as ongoing, and the other (Martin 2000) placed in Studies Awaiting Assessment. Further information obtained from trialists resulted in the exclusion of four trials that had been previously listed as ongoing studies. Three (Brownson 2001; Hems 2000; Wallace 2000) of these had been set up as a multi-centre study to test the Halder nail (Halder 2001), and one (Welsh 2000) had been set up to compare surgical with conservative treatment. |
| 3rd version (minor update)<br>Issue 3, 2002 | As above | Note: this update included some changes to the Discussion in response to comments received from an external reviewer. |
| 4th version (substantive update)<br>Issue 4, 2003 | This update had 12 included studies, 11 excluded studies, and 4 studies listed as ongoing. | Of four newly identified studies, one (Wirbel 1999) was included, one (de Boer 2003) excluded, and two (Frostick 2003; Shah 2003) are listed as ongoing. The other newly included trial (Hodgson 2003) was formerly listed as an ongoing trial. A trial (Martin 2000), previously in 'Studies awaiting assessment', was excluded. Limited additional findings from newly identified trial reports were included for Hoellen 1997. |
| 5th version (minor update)<br>Issue 2, 2007 | This update had 12 included studies, 12 excluded studies, 5 studies listed as ongoing and 4 pending assessment. | Six new studies were identified, one (Fjalestad 2007) was listed as ongoing, one (Flannery 2006) was excluded and the other four were placed in 'Studies awaiting assessment', pending further information. |
| 6th version<br>(new citation update)<br>Issue 12, 2010 | This update had 16 included studies, 18 excluded studies, 11 studies listed as ongoing and 4 pending assessment. | Sixteen new studies were identified. Of these, one (Fialka 2008) was included, four (Gradl 2009; Mechlenburg 2009; Wan 2005; Yang 2006) were excluded, 10 (Brorson; Guy; Helsinki; HURA; Liverpool; Loma Linda; Pelet; ProCon; ProFHER; Ring) were placed in ongoing trials and one (Luo 2008) awaits assessment. New reports or information resulted in the inclusion of three more trials (Agorastides 2007: former ongoing study Frostick 2003; Fjalestad 2010: former on- |

(*Continued*)

| | | |
|---|---|---|
| | | going study Fjalestad 2007; and Lefevre-Colau 2007: formerly Lefevre-colau 2006, a study awaiting assessment); and the exclusion of two studies (Bing 2002: former ongoing trial Sharma 2000; Dias 2001: former ongoing trial Dias 2001 and study awaiting assessment Der Tavitian 2006). |

## Appendix 4. Previous acknowledgements and contribution of authors

### Acknowledgements

We thank Panos Thomas for his contribution to the protocol, and Linda Digance, Christopher Muller and Sonia Stewart for foreign translations. We thank Bill Gillespie, Peter Herbison, Leeann Morton, David Sonnabend, John Stothard, Marc Swiontkowski and Janet Wale for their help at editorial review of the first version. We thank David Sonnabend for sharing his observations on the second version, and Bill Gillespie for his suggestions for incorporating these into the third version. We thank Lesley Gillespie, Peter Herbison, Nicola Maffulli and Janet Wale for their help at editorial review of the fourth version. We thank Joanne Elliott, Bill Gillespie, Lindsey Shaw and Janet Wale for their contributions at editorial review of the fifth version.

We thank Lesley Gillespie for her help in developing the revised search strategy and trial retrieval for the updates and advice on presentation. We thank Laurent Audige of the AO-ASIF Foundation and Anette Blümle of the German Cochrane Centre for the supply of several trial reports.

We thank Alastair Gibson for his major contributions to the first four versions of this review.

We thank the following for further information on their research in this area before the current update: Cathy Booth, Stig Brorson, Peter Brownson, Piet de Boer, Joe Dias, Tore Fjalestad, Mark Flannery, Tim Hems, Stephen Hodgson, Roo Kulkarni, Shea Palmer, Rajiv Sharma and Robin Turner.

Helen Handoll's work on the first version of the review was supported by the Chief Scientist Office, Department of Health, The Scottish Office, UK. Her work on the first and second updates was supported by the East Riding and Hull Health Authority, UK.

### Contribution of authors

Rajan Madhok (RM) and Panos Thomas initiated the review and wrote the protocol. Helen Handoll (HH) searched for trials and provided a set of potential studies for inclusion. Alastair Gibson (JNAG) and HH assessed trial quality, tabulated the data and were the main authors of first published version of the review. JNAG, HH and RM contributed to the final manuscript.

For the first and third (both substantive) updates, Helen Handoll initiated the update by extending the search for trials and relevant materials, contacting trialists and preparing the first drafts. JNAG, HH and RM assessed the newly identified trials and contributed to the final manuscripts. All authors contributed to rewording of the discussion in the second minor update (amendment).

For the fourth (minor) update, Helen Handoll initiated the update by extending the search for trials and relevant materials, contacting trialists and preparing the first drafts. RM performed study selection and contributed to the final manuscript.

## WHAT'S NEW

Last assessed as up-to-date: 18 May 2010.

| Date | Event | Description |
|---|---|---|
| 1 November 2010 | New citation required and conclusions have changed | 1. Conclusions changed to accommodate findings of the new comparisons.<br>2. Change in authorship. |
| 1 November 2010 | New search has been performed | In this update, published in Issue 12, 2010, the following changes occurred:<br>1. The full search was updated to March 2010; with other searches extended to August 2010.<br>2. Sixteen new studies were identified, of which one was included, four were excluded, 10 were placed in ongoing trials and one awaits assessment. New reports or information resulted in the inclusion of three more trials and the exclusion of two studies that had been identified previously.<br>3. Review methods and formatting were updated.<br>4. Background and Discussion revised and updated.<br>5. Changes made to the conclusions. |

## HISTORY

Protocol first published: Issue 1, 1996

Review first published: Issue 1, 2001

| Date | Event | Description |
|---|---|---|
| 5 August 2008 | Amended | Converted to new review format. |
| 28 September 2007 | New search has been performed | The fourth update (Issue 2, 2007) included the following:<br>1. Trial search extended from May 2003 to September 2006.<br>2. Identification of six new studies: one of which was placed in 'Ongoing studies', one was excluded and the other four are in 'Studies awaiting assessment', pending further information or publication.<br>3. Various adjustments were made to text, tables and presentation of the analyses to conform to revised methodology and the Cochrane Style Guide: the 'Synopsis' was amended to a 'Plain language summary'; the 'Abstract' was shortened; the 'Objectives' were reworded; methodological quality scores of individual criteria are no longer summed; all totals were removed from the Analyses (Forest plots) and the number of Analyses were reduced by presenting similar outcome measures (e.g. complications) together from the same trial. |

(*Continued*)

| | | |
|---|---|---|
| | | There was no change to the conclusions of the review.<br>Please see 'Notes' for details of previous updates |
| 12 August 2003 | New search has been performed | The third update (Issue 4, 2003) included the following:<br>1. Trial search extended from November 2001 to May 2003.<br>2. Inclusion of two new trials, one of which had been listed as ongoing.<br>3. Inclusion of two new ongoing trials.<br>4. Exclusion of four trials previously listed as ongoing.<br>5. One trial, previously in pending, was excluded.<br>6. Addition of limited findings from newly identified trial reports of an already included trial.<br>7. The conclusions of the review were slightly modified to include the possibility of immediate physiotherapy, without immobilisation, for some types of undisplaced fractures. |
| 8 May 2002 | Amended | The second update (Issue 3, 2002) included some changes to the Discussion in response to comments received from an external reviewer. |
| 15 February 2002 | New search has been performed | The first update (Issue 2, 2002) included the following:<br>1. Trial search extended from July 2000 to November 2001.<br>2. Inclusion of one new trial.<br>3. Inclusion of one new ongoing trial.<br>4. Exclusion of four trials previously listed as ongoing.<br>5. One trial excluded and another placed in pending.<br>6. Addition of material from a newly available epidemiological study and commentary on a newly available systematic review.<br>There was no change to the conclusions of the review. |

## CONTRIBUTIONS OF AUTHORS

For the fifth update (sixth version), Helen Handoll initiated the update by extending the search for trials and relevant materials, contacted trialists, revised text and tables to conform to new methodology and formatting requirements, performed risk of bias assessment for already included trials and prepared the first full draft. Both authors piloted forms, performed study selection, and assessed risk of bias and extracted data for the new included trials. Benjamin Ollivere provided feedback on interim drafts and contributed to the final manuscript.

Helen Handoll is the guarantor of the review.

The contributions of authors summaries for previous versions of the review are presented in Appendix 4.

## DECLARATIONS OF INTEREST

None known. Helen Handoll is a member of the trial management group of an ongoing trial (ProFHER); arrangements will be made for independent review of this trial when completed.

## SOURCES OF SUPPORT


### Internal sources

- University of Teesside, Middlesbrough, UK.

### External sources

- No sources of support supplied


## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

### Current update

Most of the changes to methods reflected the uptake of new methodology and reporting as described in the Handbook (Higgins 2008b). These include risk of bias assessment and more explicit reporting of data analysis and collection. Types of outcome measures have been revised to define primary and secondary outcomes. Patient-reported measures of upper-limb function and a separate category for serious adverse events have been added.

### Previous update

The order of the main categories of outcome measures was altered in Issue 2, 2007 to reflect the greater priority given to functional and clinical outcomes.

## INDEX TERMS

### Medical Subject Headings (MeSH)

Bandages; Fracture Fixation [methods]; Physical Therapy Modalities; Randomized Controlled Trials as Topic; Shoulder Fractures [surgery; *therapy]; Treatment Outcome

### MeSH check words

Adult; Humans